CLINICAL AND RADIOLOGICAL EVALUATION OF FLAPLESS DELAYED LOADING VERSUS CONVENTIONAL DELAYED LOADING OF IMPLANTS IN PARTIALLY EDENTULOUS PATIENTS – ONE YEAR RANDOMIZED, PROSPECTIVE FOLLOW UP STUDY

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CERTIFICATE

This is to certify that **Dr.Ria Maria Jain**, Postgraduate student in the Department of Periodontics, J.K.K.Nattraja Dental College and Hospital, Komarapalayam has done this dissertation titled **"CLINICAL AND RADIOLOGICAL EVALUATION OF FLAPLESS DELAYED LOADING VERSUS CONVENTIONAL DELAYED LOADING OF IMPLANTS IN PARTIALLY EDENTULOUS PATIENTS – 12 MONTHS, RANDOMIZED, PROSPECTIVE FOLLOW UP STUDY"** under my direct guidance during her post graduate study period 2009 -2012.

This dissertation is submitted to **THE TAMILNADU Dr. MGR MEDICAL UNIVERSITY,** in partial fulfillment of the degree of **MASTER OF DENTAL SURGREY, BRANCH II – Periodontics.**

DR.SUGUMARI ELAVARASU,
Professor and Head
J.K.K.N Dental college
Komarapalayam

DR.SIVAKUMAR
Principal
J.K.K.N.Dental college
Komarapalayam

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Now a days, replacing missing teeth to restore function and aesthetics is one of the main goals of dentistry. Science of implantology has made noticeable progress in replacing lost teeth.[1] The goal of modern dentistry is to restore the patient to normal contour, function, esthetics, comfort, speech, health, regardless of atrophy, disease and injury. Dentists spend much of their time in replacing missing tooth structures. Researchers have long searched for improved methods of anchoring prosthetic materials within the jaw to reconstruct an entire tooth either as a single restoration or as a support for a removable partial denture or for a fixed partial denture.

Treatment with dental implants has proven to be a predictable modality for replacing missing or failing teeth with various types of fixed or removable dental prostheses[2]. The earliest implantations, in a sense of re-implantation, dates back to pre-Christian times (saville 1913, Weinberg1948). Researchers such as Greenfield, stock Adams, Formiggini, and Dahl used a host of biomaterials and designs as insertion into bone with varying degree of success.

In the late 1950 s, Per Ingvar Branemark, a Swedish professor developed a historical breakthrough in medicine. He achieved a bone to implant apposition that offered strength to cope with load transfer .He called the phenomenon “osseointegration”. The first patient treated by means of this approach is in 1965. Branemark along with Adell (1981), Albrektsson (1985) developed a two stage implant system for oral endosseous implantations that consisted of a screw made of pure titanium and appropriately standardized instrument and connectors. Today implant therapy represents an effective treatment option for replacing missing teeth[3]

Mainly three types of implant placements are present –delayed implant placement, early implant placement, and immediate implant placement. Single tooth implants can be placed either in healed extraction sites (delayed) after 3-6 months or fresh extraction sockets (immediate) or one to few weeks after the healing (early)[4] or immediately after extraction in immediate placement.[5,6]

In one stage surgical procedure, the flaps were sutured around the polished neck of implants avoiding the need for second stage surgical intervention by giving a healing abutment.[7] A two stage surgical technique was originally advocated in order to optimize the process of new bone formation and remodeling, following implant placement. Implants were submerged and left to heal load free for 3-4 months in mandible and 6 to eight months in maxilla.[8] Following this procedure a second stage surgery was needed to connect the healing abutment to implant, holding the future prosthesis. After the second intervention, 4-6 weeks of healing period was needed for proper contouring of the soft tissue around a healing abutment, to allow for a predictable esthetic outcome.[9]

Originally the two stage surgical approach using submerged implants was advocated with the concept that a healing period of at least 3 to 6 months should be allowed to provide a load free environment and undisturbed healing for successful osseointegration. However, implant therapy utilizing the one stage surgical protocol (nonsubmerged implants) has also been available, and its successful use has been proven comparable to the two-stage surgical

approach. In mandible 3-4 months are needed for successful osseointegration and in maxilla it is 6-8 months.[7,10]

Previous studies have demonstrated that flap reflection often results in gingival recession and bone resorption around natural teeth. To minimize the possibility of postoperative peri-implant tissue loss and to overcome the challenge of soft tissue management during or after surgery, the concept of flapless implant surgery has been introduced and clinically applied.[11]

Advantages of the flapless implant surgery, included less traumatic surgery, decreased operative time, accelerated post surgical healing, fewer post operative complications, increased patient comfort and satisfaction and preservation of soft tissue profiles. Flap reflection can cause postsurgical bone resorption and soft tissue recession.[11]

However pre-requisite for flapless implant surgery include sufficient bone width and height. Adequate keratinized soft tissue and absence of significant tissue undercuts. But if the amount of bone is limited, the surgeon will work blindly and bone perforation may occur. So proper bone sounding, bone mapping and measurement of bone width and length and radiographic evaluation should be done before implant placement to avoid perforation.[12]

In conventional flap reflection method flap is elevated to visualize better the bone sites, anatomic land marks can be clearly identified and protected (foramina, lingual undercuts, or maxillary sinuses). If amount of available bone is limited, flap elevation is advised, it maximizes bony contact and minimizes the risk of bone fenestration.[13]

The problems that can be associated with flap reflection method is post surgical bone resorption, gingival recession, waiting period for healing, esthetic problems persist until the delay of definitive restoration, morbidity and discomfort, requires suturing and inconvenience to patient.[13]

In implants the criteria for success should involve the establishment of a soft tissue contour with intact interproximal papilla and a predictable gingival outcome. The interdental bone and papilla height were co-related according to the distance from contact point to crestal bone. If the measurement from the contact point to the crest of the bone was 5 mm, the papilla would present almost 100 %. If the distance was greater than 6mm, the papilla would present 50 % or less.[14] Based on this data, the clinician attempted to maintain 5 mm of distance from the contact point to the crestal bone, when placing the implant.

Adequate zone of keratinized mucosa measures as 2mm of width, of 1 mm was to be attached gingiva.[15] The attached gingiva is necessary for the maintenance of gingival health and prevention of periodontal disease progression.[16] Peri–implant and periodontal tissues may differ in their resistance to bacterial infection because supracrestal collagen fibers in implants are oriented in parallel rather than a perpendicular configuration. This creates a much weaker mechanical attachment compared to natural teeth. Thus, adequate zone of keratinized mucosa adjacent to the implant has to be maintained.[17]

The influence of mucosal thickness on crestal bone loss around implant has been reported recently. And it is necessary, that the minimum of

3mm of peri-implant mucosa is required for the stable epithelial connective tissue attachment around implants. A thick mucosa was resilient and therefore prone to pocket formation, while a thin mucosa was friable and thus often prone to gingival recession.[18,19]

The purpose of this study is to evaluate the width of the keratinized gingiva, thickness of peri-implant mucosa, height of interproximal papilla, probing depth, soft tissue condition and bone loss around the single tooth implants in flapless delayed loading versus conventional delayed loading of implants in partially edentulous patients.

1) To evaluate and compare the clinical and radiological parameters of flapless delayed loading versus conventional delayed loading of implants placed in partially edentulous patients

2) To assess if any significant correlations exist between width of keratinized mucosa and health of peri-implant tissues around the flapless delayed loading group versus conventional delayed loading group

Starting as early as the time of the ancient Egyptians in 2500 B.C., evidence exists of attempts at stabilization of periodontally compromised teeth with the use of gold ligature wires.

500 B.C- The Etruscan population utilized soldered gold bands incorporating pontics from animals to restore masticatory function as a bridge.

300 A.D- The Phoenican population developed a fixed bridge replacement utilizing carved ivory teeth stabilized by gold wire.

600 A.D- The first evidence of the use of implants was seen in the Mayan population. A mandible was found in 1931 by Dr. Wilson Popenoe in Honduras. It had three pieces of shell/ carved stone in place of the natural lower incisors. This fragment is the earliest example of a presumably successful endosseous alloplastic implant operation on a living person. The specimen was subjected to radiography by Babbio in 1970, which showed compact bone formation around two of the implants.

800 A.D- Quartz and Amethyst tooth implants were used in humans and the Inca skull kept in a museum in Peru showed thirty two teeth implants. 936-i0i3, Aibucasis de Condue, an Arabian surgeon, used implants made from ox bone. Abulcasiz di Zabra used implants made from cow's bone.

1809- Maggioto described the process of fabricating and inserting gold roots as a support system to the teeth. The implant was constructed by soldering three gold pieces in an approximate proportion of the socket created by the extraction of the tooth it would replace.

1913 - Greenfield, an American, developed the 'Greenfield Cage' endosseous implant.

1920- Leger Dorez introduced tubular extension implant.

1939- Strock brothers from Boston placed vitallium screw type implants to provide anchorage for replacement of a missing tooth.

Mid 1940's Manlio S Formiggini, an Italian, designed a spiral implant constructed by bending stainless steel or tantalum wire bent back upon it to form a series of spirals.

1948- Strock brothers placed the internally threaded root form submergible implant.

1943- Dahl first suggested the construction of the sub-periosteal implant. The original design was rather bulky with flat abutments and screws over the crest of the ridge.

1948- Goldberg and Gershkoff refined the subperiosteal implant with an extension of the framework to the external oblique region.

1950's- Bodine in his framework design, incorporated secondary struts, and screw holes were located in regions of bone density.

1952- Lew described the use of a direct impression technique. In addition fewer struts were utilized in the framework over the crest of the ridge.

1959- Lee described the progress and evolution of subperiosteal implants and further modified the framework to incorporate maximum

strength and minimum bulk. Simple tapered abutments were utilized as the transmucosal abutments.

1950's- Lee introduced the use of an endosseous implant with a central post and circumferential extensions.

1958- Thomas T. Kieman made a buried implant in stainless steel, internally threaded and having the shape of and slightly larger than the root of an incisor.

1959- Raphael Chercheve, a Frenchman, also modified Formiggini's original design.

1963- Scialom described the use of tripodal endosseous pin arrangement.

1965- Branemark followed the sleep away design of Chercheve and claimed to acquire "osseous-integration" after leaving the implant buried for many years leading to "bone-fusion". The major breakthrough in implant success, which ultimately led to the very successful materials & techniques now being employed, was made in l952 by Per-Ing-var Branemark, in Sweden, while investigating wound healing. By chance it was discovered that titanium was biocompatible and when surgically placed in bone, direct bone contact and complete healing occurred. This reaction of the bone to titanium was termed "osseointegration".

Branemark's great contribution to implantology was his insistence that the bone had to be approached with a very low speed handpiece to reduce bone damage and that an implant if buried for several months and placement performed under ideal surgical procedures would osseointegrate. The first screw shape implants were placed in patients in 1965. The technique was kept under research conditions and refined until 1985 when it was released to suitably trained practitioners.

Flap implants

Use of the Branemark system (Nobelpharma AB, Goteborg, Sweden) to provide support for the replacement of single tooth was an inevitable treatment opinion that has recently evolved. The method is based on gentle surgical introduction of a pure titanium implant into the vital bone and the biocompatibility of titanium, which permits osseointegration. Clinical data concerned with the soft tissue response to transepithelial titanium abutments attached to the implant have confirmed a clinical and histological status comparable to that of a natural tooth.

Albrektsson. T et al., (1988)[20] evaluated the success rate of implants based on success criteria. The success criteria included absence of implant mobility, absence of radiolucent zones on X- rays, and an annual bone loss of less than 0.2 mm after one year. It was concluded that osseointegrated implants, if inserted according to the guidelines of Branemark, could achieve a high degree of clinical success.

Van Steevenberg D et al., (1990)[21] has studied 107 applicability of oral implants in the rehabilitation of partial edentulism on 558 fixtures. it is recogonized that the functionally loaded dental implant averages approximately 1.0.mm of bone loss in the firsr year, and at least 0.10 mm of bone loss per year in function afterward.

Anders. A et al., (1994)[22] evaluated 93 single tooth implants placed using two stage surgical protocols. Only two implants were lost; one before the abutment operation and one during the first year in function. From this clinical study, it can be concluded that implants were an effective treatment alternative offering promising results for the replacement of a missing single tooth.

Harris. D et al., (1994)[23] conducted a study of 107 delayed implants in 92 patients for 3 years. This prospective, multicenter study of single Branemark system implants (Nobelpharma AB, Goteborg, Sweden) was initiated in 1987. Marginal bone resorption remained at levels less than 0.1 mm annually, it was a significantly reduced rate from that reported after 1 year. Titanium abutment screws had favorable outcomes than gold.

Andersson. B et al., (1995)[24] estimated the success rate of 102 CeraOne implants placed in single edentulous site, using two stage surgical procedures for 3 years. It was proven that the system achieves good esthetic results and avoids the complications of screw loosening and fistula formation. The author concluded that utilization of the CeraOne system provided good esthetic results.

Henry. PJ et al., (1996)[25] conducted a prospective 5-year multicenter study of delayed single tooth implants for 5 years. Plaque and gingival indexes showed similar pattern of good health around both natural teeth and titanium abutments. The marginal bone loss during the 5 year period did not exceed 1 mm as a mean, for all implants analyzed. The Branemark single tooth implants were highly predictable in this study.

Jemt. T et al., (1997)[26] evaluated regenerated gingival papilla after a single tooth implant replacement. The interproximal gingival papilla was assessed using the Jemt index. The results indicated that significant spontaneous regeneration of papillae was achieved after a mean follow-up period of 1.5 years. They concluded that the proposed index allows scientific assessment of soft tissue contour adjacent to single-implant restorations.

Hafeli U. et al., (1998)[27] evaluated post surgical crestal bone levels adjascent to non submerged dental implants and numerous longitudinal and radiographic studies have identified and examined the initial bone remodeling that occurs with a one stage implant system have reported that a mean of 0.6mm of radiographic bone loss within the first year of placement.

Chang M et al., (1999)[28] compared the clinical conditions between an implant supported single tooth and the contralateral tooth. The results revealed that, the implant supported crown showed increased bleeding on probing, probing depth, and higher frequency of mucositis score. The longitudinal evaluation of the papilla adjacent to the implant crown showed an improved proximal soft tissue fill at the follow-up examination.

Bahat. O et al., (2000)[29] evaluated the branemark system implants in the posterior maxilla, a clinical study of 660 implants followed for 5-12 years demonstrating successful outcome of implant dentistry. Historically, the protocol for dental implants has been to place them in healed sockets using conventional delayed loading.

Tarnow et al., (2000) [30] evaluated the crestal bone height to horizontal distance between 2 implants in relation to the presence of papilla. Of the 36 patients studied, the radiographs were evaluated between 1 and 3 years. Implants were categorized into groups based on whether the distance was greater or less than 3 mm; a predetermined value selected by the authors. It was implied that increased crestal bone loss would occur if the inter-implant distance was less than 3 mm.

Choquet. V et al., (2001)[14] evaluated the papilla levels adjacent to single implants by a clinically and radiographic method. They concluded that, if the measurement from the contact point to the crest of the bone was 5 mm or less, the papilla would present almost 100%. If the distance was ≥6 mm, the papilla would present 50% or less. The results clearly showed that there was direct influence of the bone crest on the presence or absence of papilla between implants and adjacent teeth.

Kan. J et al., (2003)[31] evaluated the dimension of peri-implant mucosa of maxillary single tooth implants. The dimensions of peri-implant mucosa in the thick biotype were significantly greater than the thin biotype. They concluded that the level of the interproximal papilla of the implant was

independent of the interproximal bone next to the implant, but it was related to the interproximal bone level adjacent to teeth. The thick peri-implant biotype had greater peri-implant mucosal dimension.

Gastaldo. JF et al., (2004)[32] evaluated the effect of vertical and horizontal distances between adjacent implants and between a tooth and an implant on the incidence of interproximal papilla. They concluded that the ideal distance from the base of the bone crest between adjacent implants were 3 mm and, between a tooth and an implant were 3mm to 5 mm. Ideal lateral spacing between implants and between tooth and implant is 3 to 4 mm.

Henriksson. K et al., (2004)[33] measured the soft tissue volume in association with single-implant restorations. They concluded that buccal tissue was increased significantly after placement of abutment and crown. This increase of buccal contour was reduced after 1 year. Furthermore, no relationship was established between the presence of papilla and the distance between the contact point and underlying bone crest.

Appleton. R et al., (2005)[34] evaluated a radiographic assessment of progressive loading on bone around single osseointegrated implants in posterior maxilla. The progressive loaded crowns were placed in infra-occulsion for the first 2 months, light occlusion for the second 2 months, and full occlusion for the third 2 months. They concluded that the peri-implant bone around progressively loaded implants demonstrates less crestal bone loss than the bone around implants placed conventionally into full function with increased bone density.

Gert et al .; (2006)[35] evaluated 20 patients 11 male and 9 female in mandibles and in this study the surgical site is exposed and an inter-foraminal mucoperiosteal flap is elevated and reflected. This procedure may be complicated by post operative infection, dehiscence of the surgical wound, and nuerosensory disturbances.

Watzak. G et al., (2006)[36] evaluated radiological and clinical parameters of two types of implants with respect surfaces of implants. This study was followed for 33 months and peri-implant bone loss was assessed using panoramic radiograph. In this method, implants were placed at crestal bone level and bone loss was measured from implant platform to crest of bone. They concluded that both implants produced excellent results.

Misch. C et al., (2008)[37] evaluated posterior single tooth implant survival and long-term conditions of the adjacent teeth for a 10 year period. Long term adjacent tooth conditions like decay, endodontic therapy and extraction during follow up visits were assessed. They concluded that the use of single tooth implants as replacement for posterior missing teeth is viable long term treatment and adjacent natural teeth complications are minimal for as long 10 year after implant insertion.

Bouri. A et al., (2008)[16] conducted a study to determine whether an association exists between the width of keratinized mucosa and the health of implant-supporting tissues. Implants with a narrow zone of keratinized mucosa were more likely to bleed upon probing, even after adjusting for Plaque Index, smoking, thickness of the gingiva, and time since implant

placement. They concluded that increased width of keratinized mucosa around implants is associated with lower mean alveolar bone loss and improved indices of soft tissue health.

Shahindi. P et al., (2008)[38] compared the efficacy of a new uncovering technique with that of the conventional uncovering technique for papilla generation. Implants of the test group were uncovered by the new technique and implants of the other group were uncovered by the conventional technique (simple mid-crestal incision). Based on this study, it appears that over the course of 6 months, the new surgical approach for uncovering leads to a more favorable soft tissue response.

Linkevicius. T et al., (2009)[18] evaluated the influence of gingival tissue thickness on crestal bone loss around dental implants after a 1-year follow-up. According to tissue thickness, the test implants were divided into A (thin) and B (thick) groups. They concluded that initial gingival tissue thickness at the crest may be considered as having a significant influence on marginal bone stability around implants. If the tissue thickness is 2.0 mm or less, crestal bone loss up to 1.45 mm may occur, despite a supracrestal position of the implant-abutment interface.

Kyun. Y et al., (2010)[39] evaluated the prognosis of single molar implant restorations. They concluded that risk for failure of maxillary and mandibular single molar implants was high and the possibility of developing prosthetic complications during loading is also high. Therefore, to minimize

the cantilever, implants must be placed precisely and followed up carefully and maintained for a long period of time.

FLAPLESS IMPLANTS

Wilderman et al; (1965)[40] in his study repair of a dentogingival defect with a pedicle flap found that when a tooth is lost, the blood supply from the periodontal ligament disappears, and blood is supplied only from soft tissue and bone. Cortical bone is poorly vascularized in contrast to marrow bone. When soft tissue flaps are reflected for implant placement, the blood supply from the soft tissue to the bone (supraperiosteal blood supply) is also removed, leaving only poorly vascularized cortical bone without a part of its vascular supply, ultimately prompting bone resorption during the initial healing phase.

Ramfjord et al; (1968)[11] studies have demonstrated that flap reflection often results in gingival recessison and bone resorption around natural teeth. To minimize the possibility of post operative peri-implant tissue loss and to overcome the challenge of soft tissue management during or after surgery, the concept of flapless implant surgery has been introduced and clinically applied.

Branemark et al;(1997)[13] evaluated osseointegrated implants in the treatment of the edentulous jaw and found that traditionally osseointegrated dental implants can kept load free for 3-4 months in the mandible and 6-8 months in the maxilla. It would be beneficial to reduce the healing period without jeopardizing implant success.In flapless Patients receives implant

placement with minimal surgical intervention, less discomfort and shorter treatment time at lower cost.

Ansari et al; (1998)[41,42] evaluated placement of dental implant without flap surgery and found out that implant placement without mucoperiosteal flaps has been associated with high success rates and has shown several advantages such as reduction in intra - operative bleeding and patient discomfort. Bone resorption of varying degrees can occur subsequent to soft tissue flap reflection.

Buser et al; (1999)[43] evaluated clinical experience with one stage nonsubmerged dental implants and successful results shown in several animal and longitudinal studies using a one stage surgical protocol and favorable outcome enhancing esthetics and function in addition to good osseointegration.

Tarnow et al; (2001)[44] evaluated clinical and radiographic evaluation of papilla level adjacent to single tooth dental implant and reported that post – surgical tissue loss can occur from flap reflection implying that flap surgery for implant placement may negatively influence implant esthetic outcomes especially in the anterior maxilla.

Campello et al; (2002)[45] in his study flapless implant surgery: A longitudinal clinical retrospective analysis in recent years reported that flapless implant surgery is a predictable procedure with high success rates, if patients are appropriately selected and an appropriate width of bone is available for implant placement.

Camara et al; (2002)[45] evaluated flapless implant surgery ;A 10 year clinical retrospective analysis suggested that flapless implant surgery as a treatment modality for the preservation of soft tissue and for increasing patient comfort and satisfaction.

Becker et al; (2005)[13] conducted a study in 79 implants placed in 57 patients, the cumulative success rate using a minimally invasive flapless method was 98.7% after two years. Results showed lessened surgical time, minimal changes in crestal bone loss, probing depth, inflammation, minimal bleeding and post - operative discomfort.

Tarazi et al; (2005)[46] evaluated intra-operative computerized navigation for flapless implant surgery in the edentulous mandible, the implants were placed, the flap was sutured and kept incision line away from the implants, there by possibly preventing infection. He found out that peri-implantitis did not occur in the flapless group.

Becker et al; (2006)[47] esstimated the histological evaluation following flapless and flap surgery and found out that flapless or minimally invasive surgery offers clinician the possibility of placing implants in less time, less bleeding and post-operative discomfort for the patient.

Fortin et al; (2006)[13] assessed the effect of flapless surgery on pain experienced in implant placement using an image guided system and found that flap elevation is associated with some degree of morbidity and discomfort and also requires suturing. There are situations in which flap elevation may

not be necessary if estimated amount of bone is adequate for receiving dental implants and the risk of complications is minimal.

Tae-Ju-oh et al; (2006)[48] evaluated the effect of flapless implant surgery on soft tissue profile. This study suggest that flapless implant surgery provides esthetic soft tissue results in single tooth implants in delayed loading.

Shotwell et al; (2006)[13] evaluated effect of flapless implant surgery on soft tissue profile. Only 20 carefully selected patients were treated after a thorough diagnostic analysis. Retrospective and prospective studies have suggested that in many instances, it is possible to place dental implants successfully without elevating a flap, comparing flapless procedures with open flap implant placement showed that patients who underwent flapless implant placement suffered less post-operative pain for a shorter period of time.

Chang et al; (2007)[49] examined the effect of flapless implant surgery on crestal bone loss and osseointegration in a canine mandible model and achieved the results that the osseointegration was greater at flapless sites than flaps. The mean peri-implant bone height was greater at flapless sites than at sites with flaps.

Tae- ju- oh et al (2007)[11] evaluated two clinical cases of single tooth implants in the esthetic region in which systematic approaches to flapless implant surgery using immediate or delayed loading protocol are described. Thus reported that appropriate case selection and well tailored surgical guides with sound surgical and prosthodontic protocols are considered to be key elements in the success of flapless implant surgery.

Cannizzaro et al; (2008)[8] compared the efficacy of immediate functionally loaded implants placed with a flapless procedure versus implants placed after flap elevation and conventional load free healing. The results revealed that implants can be successfully placed in flapless and loaded immediately without compromising success rates; the procedure decreases treatment time and patient discomfort.

Jeong et al;(2008)[50] reported that when implants were placed without flap elevation, the amount of osseointegration and the bone height around the implants were significantly greater than in implants placed with flap elevation. However, an appropriate width of the alveolar ridge must be available for implant placement using a flapless technique.

Seoung et al; (2008)[50] conducted a study bone healing around implants following flap and mini flap surgeries a radiographic evaluation and found out that results indicated that the mean crestal bone loss was approximately 1 mm more in the implants placed, with the flap procedure than in the implants placed with the flapless procedure.

Jung et al; (2009)[51] evaluated blood vessels of the peri-implant mucosa a comparison between flap and flapless procedures and results showed that the supra-crestal connective tissue lateral to the implant was found to be more richly vascularized in the flapless group than in the flap group, the flapless procedure may increase the vascularity of the peri-implant mucosa.

Tae et al; (2009)[52] evaluated morphogenesis of peri-implant mucosa, a comparison between flap and flapless procedures in the canine and the results indicated that gingival inflammation, height of junctional epithelium, and bone loss around non-submerged implants can be reduced when implants are placed without flap elevation.

Kusek et al; (2009)[53] in his study, flapless implant surgery with the esthetic temporaries found out that dental implants placed by raising a surgical muco-periosteal flap can cause a number of complications of concern such as tissue recession, crestal bone loss and scarring. So current trend is to develop techniques that can provide function, esthetics and comfort with minimally invasive surgical approach of flapless implant surgery using tissue punch technique.

Nadine et al.; (2009)[54] evaluated flapless surgery in 778 patients and its effect on dental implant outcomes and found out that flapless surgery has several potential advantages, including reduction of complications like swelling and pain, reduction of intra operative bleeding ,surgical time and no need of suturing, preservation of soft and hard tissues and maintenance of blood supply.

Deepak et al; (2010)[55] assessed the efficacy of flapless implant surgery on soft tissue profile and clinical outcomes of flap comparing immediate loading implants to delayed loading implants and the results of this study indicated that flapless implant surgery demonstrate enhancement of implant esthetics and flapless implant surgery can be used to preserve soft tissue profile and increase patient satisfaction.

Arndt happe et al; (2010)[56] conducted key hole access expansion technique for flapless implant and he found that favorable, esthetic and functional results can be achieved which is easy to perform, safe and minimally invasive.

This study was designed and conducted by the Department of Periodontics, JKKN Dental College and Hospital, Komarapalayam, to Evaluate the clinical and radiological parameters of flapless delayed loading and conventional delayed loading in single tooth implant placement.

MATERIALS

A Hi – Tech implant (Life care implants) made up of titanium with self-threaded internal hex and selective integrated surface were used. The four diameters and prosthetic platforms (standard and wide platform) of implants are available with variable diameters and lengths 3.3, 3.75, 4.2, 5.0 mm and 8, 10, 11.5, 13, 16 mm. it has round end that protects and prevents sinus membrane perforation.

METHOD

STUDY- DESIGN

A randomized, prospective clinical trial was conducted to evaluate the clinical and radiological parameters of flapless delayed loading and conventional delayed loading group in single tooth implant placement. The ethical clearance was obtained from the institutional ethical board prior to the start of the study. 9 (7 females, 2 males) patients of both sexes with an age limit of 18 – 40 years were selected for the study from outpatient Department of Periodontics depending on the following selection criteria.

Inclusion criteria[57]

1. More than 18 years old

2. Patients with multiple edentulous areas

3. Bone thickness more than 5.5 mm

4. Extracted sites more than 6 months

5. Good oral hygiene status

Exclusion criteria[58]

1. General contraindications to implant surgery

2. Irradiation in the head and neck less than one year prior to surgery

3. Poor oral hygiene and motivation

4. Uncontrolled diabetes

5. Pregnancy and lactation

6. Substance abuse

7. Psychiatric problems

8. Lack of opposing occluding dentition in the area intended for implant placement

9. Severe bruxism and clenching

10. Active infection or severe inflammation in the area intended for implant placement

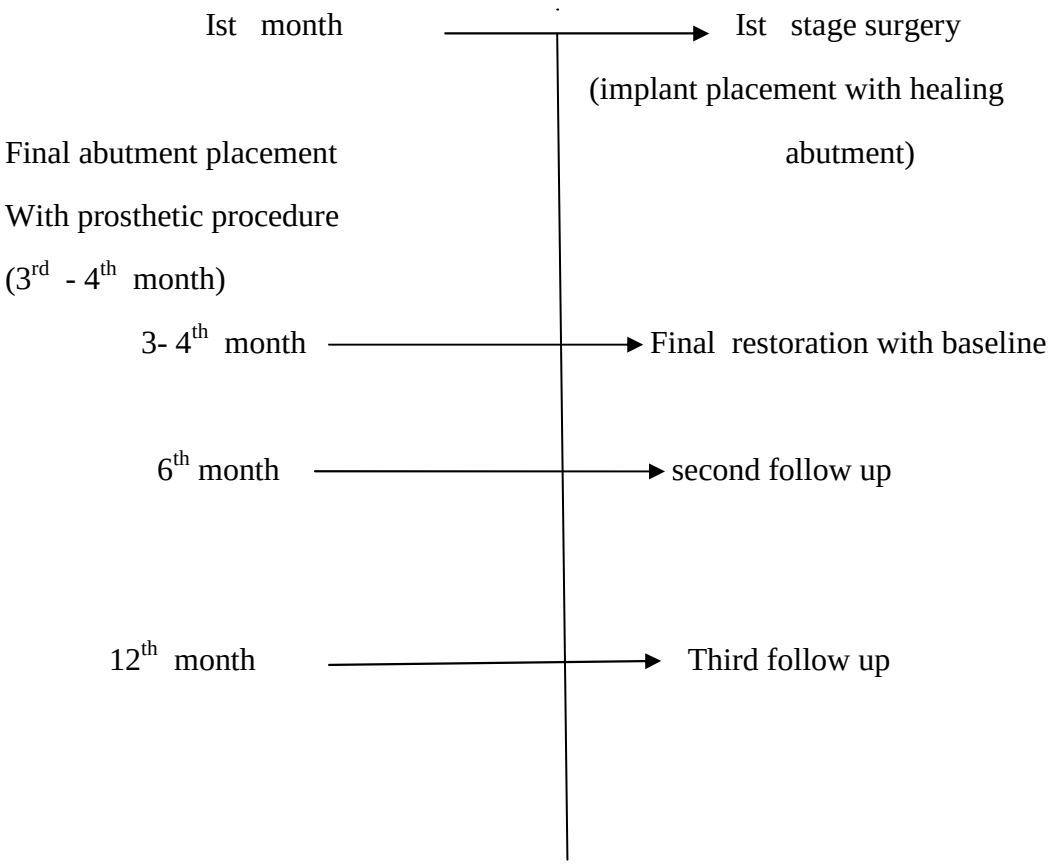
11. Presense of less than 4 mm of keratinized mucosa

12. Patients with significant undercut to prevent tissue dehisense or fenestration

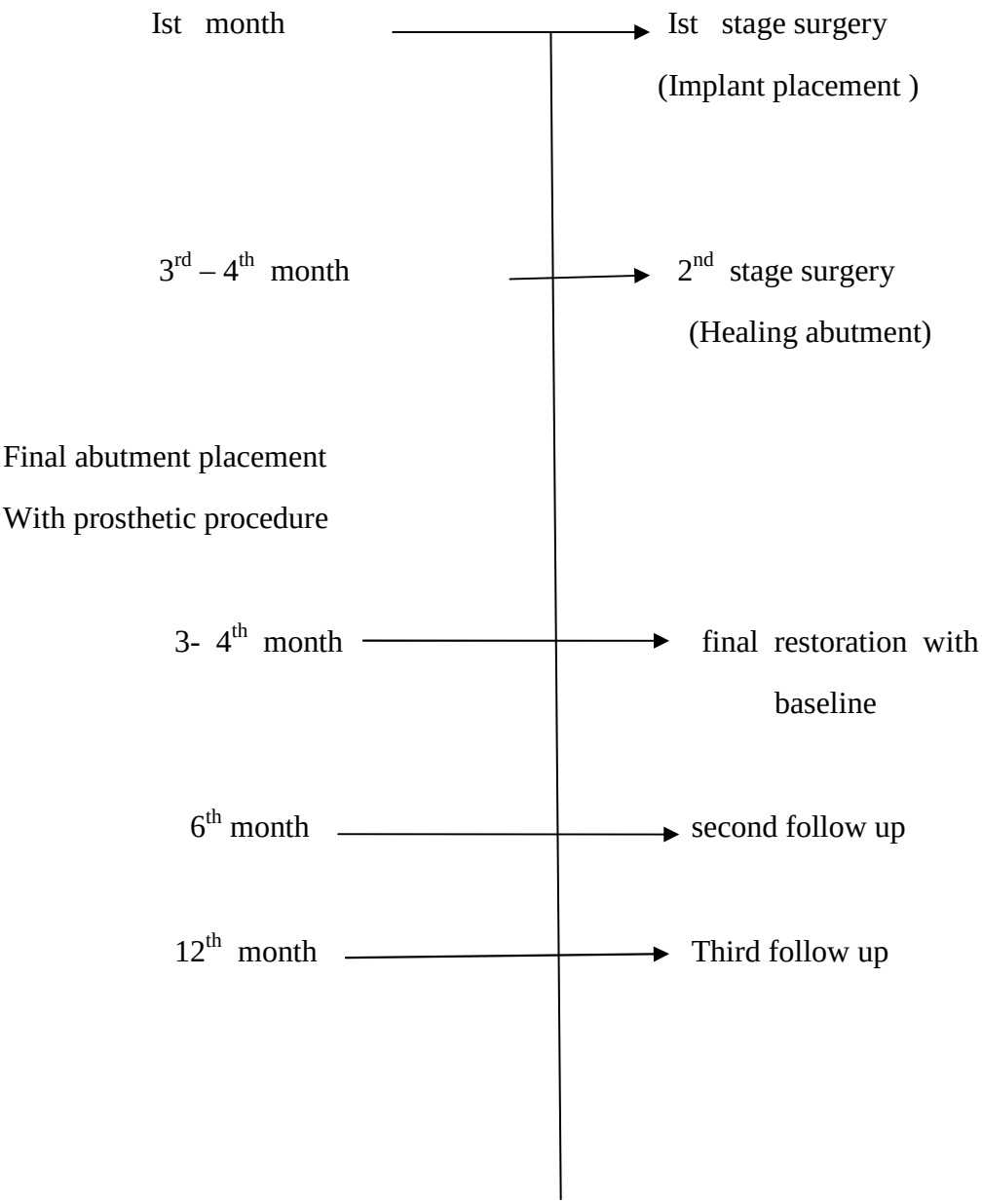
13. Presence of vital anatomic structure in very close proximity to a proposed implant site
14. Inadequate mouth opening
15. Insufficient bone quantity
16. Incomplete facial growth and teeth eruption

STUDY DESIGN

Flapless method



Conventional method with flap reflection



The nature and design of the clinical trial was explained to the patients and consent was obtained for their participation. All the patients were subjected for scaling and oral hygiene instructions were given

Criteria for grouping

The single tooth implant sites were randomly selected in either the upper or lower jaw, irrespective of whether it was an anterior or posterior region. The selected patients were categorized into two groups based on flapless delayed loading and conventional delayed loading (with flap reflection) .

Flapless delayed loading group

5 single tooth implants placed without elevating the flap by directly giving connecting healing abutment and delayed loading after 3-4 months of implant placement.

Conventional delayed loading group (with flap reflection)

5 single tooth implants placed by conventional flap reflection procedure and suturing performed and second stage surgery after 3 months for healing abutment placement and delayed loading after 3-4 months .

Pre – surgical procedure

The intraoral, panoramic radiographs were taken for the preoperative evaluation of the bone quality, implant position and orientation. The diagnostic template was made which has 5 mm ball bearing, incorporated around the curvature of the dental arch and worn by the patient during the radiographic examination, which enabled the operator to determine the amount of magnification in the radiograph. Based on the anatomical site analysis, the appropriate implant diameter and platform size was selected to best fit the single tooth edentulous area. After a preoperative workshop, a diagnostic wax-

up of the planned restoration and fabrication of a surgical stent was done before the implant surgery.[59] This stent was made for proper positioning of implant shoulder and provide an ideal emergence profile with long term peri-implant hard and soft tissue support.[60,61]

Surgical procedure

All the 10 patients were surgically prepared with routine blood investigation and radiographic assessment. Local anesthesia was induced by infiltration with lignocaine (2%) and adrenaline (1:80,000) for the both groups.

In conventional delayed group after achieving profound anesthesia, the mucoperiosteal flap was elevated with a crestal incision located approximately 2 to 3 mm toward the lingual aspect and extended to the sulcus of adjacent teeth by intra-sulcular incision.[62] This incision avoids the formation of scar tissue in the mid crestal area. The bucco-lingual and mesio-distal implant position was partially determined by the morphology of alveolus. Then the implant was placed using pilot, intermediate and final drill in such a way that cover screw was corresponding to the level of the adjacent bone. The primary closure of the wound was achieved by stabilization of the flap with simple interrupted suture 3-0 silk thread.

In flapless delayed loading group, proper bone sounding, bone mapping[63] and measurement of bone width and length and radiographic evaluations done before implant placement to avoid perforation, if the amount of bone is limited surgeon will work blindly and bone perforations may occur.

Soft tissue punching done with a soft tissue punch and 3-4mm tissue removed from the crestal area for then achieving center point for pilot drill using surgical stent as a guide. The implant was placed using pilot, intermediate, and final drill in such a way that healing abutment directly placed over the implant to condition the peri-implant soft tissues. In flapless group the second stage surgical intervention avoided by directly placing healing abutment after implant placement, so that suturing was not required and postoperative complications was minimal.[64] Direct final restoration done after 3-4 months of implant placement in this method.

Antimicrobial prophylaxis (amoxicillin 500 mg) was given one hour before surgery and continued twice daily for 7 days.[65] Post surgical analgesics (Paracetamol 500 mg + Aceclofenac 100 mg) were prescribed twice daily for one week and oral hygiene instructions were given. chlorhexidine mouthwash 0.2% also prescribed for twice daily .

In conventional group suture was removed one week after the implant surgery.[66] After 3 months of implant placement, the patients were subjected to a second stage surgical procedure. Healing abutments were mounted on to the implants in order to condition the peri-implant soft tissues for 4-6 weeks. This healing abutment connection was done by a simple midcrestal incision. Later , final abutment was selected and placed at 35 Ncm by using torque wrench. The prosthetic crown was prepared, cemented with type II GIC cement and baseline data were recorded. Then the patients were recalled for further follow up at 6th and 12^{th} month respectively.

In flapless delayed loading group, after 3-4 months of implant placement healing abutment removed already after achieving the conditioned soft tissue profile and final abutment was selected and placed at 35 Ncm by using torque wrench. The prosthetic crown was prepared, cemented with type II GIC cement and baseline data were recorded. Then the patients were recalled for further follow up at 6^{th} and 12^{th} month respectively.

CLINICAL PARAMETERS

Assessment of soft tissues at the implant site was performed after crown cementation at baseline, 6^{th} and 12^{th} month by a single examiner. At the follow up visits, the following parameters were assessed.

1. Width of keratinized mucosa (Bouri A et al.,1999)[16]
2. Thickness of peri-implant mucosa (Austria M et al.,1992)[16]
3. Papilla index (Jemt T 1997)[67]
4. Plaque index (Mombelli et al., 2004)[17]
5. Soft tissue index (Bengazi et al., 2004)[28]
6. Probing depth (Schropp et al.,2005)[9]

Evaluation methods

1) Width of keratinized mucosa:

The width of the keratinized mucosa was measured at the mid-facial aspect of each implant using UNC 15 (equinox) probe. Each measurement was made from the gingival margin to the mucogingival junction. The mucogingival junction was identified by the rolling technique, where in the

mucosa was rolled until the nonmovable portion of the attached keratinized tissue was identified.

2) Thickness of peri-implant Mucosa:

The thickness of the gingiva around dental implant was measured approximately 2 mm apical to the gingival margin on the facial aspect of the implant. After topical anesthetic application, the thickness was measured gently inserting a sterile Endo reamer with a rubber stopper, until contact of the underlying bone structure. The gingival biotype was considered thin if the measurement was lessthan 1.0 mm and thick if it measured greater than 1.0 mm.

3) Papilla index:

Clinical photographs were taken with single examiner using the same magnification and illumination. These photographs were digitalized at a resolution of 1,000 dpi. Papilla was scored using a modified scale previously described by Jemt.

The index was defined briefly as,

Score 1: No papilla was present

Score 2: Less than 50 % filling with minimal papilla present

Score 3: papilla that did not fill the space completely and had over 50% of the space filled.

Score 4: The papilla fills up the entire interdental space and had comparable filling to adjacent, non-implant restored papilla.

4) Plaque index:

The oral hygiene status was evaluated by the presence or absence of visible plaque present at the soft tissue margin. The six index teeth selected were 16,12 and 24,36,32,44.

Score 0: No plaque

Score 1: Plaque only recognized by running a probe across the smooth marginal surface of the implant.

Score 2: Plaque can be seen by the naked eye.

Score 3: Abundance of soft matter within the gingival pocket and or on the gingival margin and adjacent tooth surface.

The plaque score was obtained by totaling the four plaque scores per tooth and then divided by four. The plaque score per person is obtained by adding the plaque score per tooth and dividing by the number of teeth examined.

The scoring criteria are as follows

0.1 -1.7 _ Good

1.8 – 3.4 _ Fair

3.5 - 5.0 _ Poor

5) Soft tissue index:(Mucositis score, Bengazi et al 1996)

Indices used to asses marginal mucosal conditions around oral implants are followed,

Score 0: No color or texture alterations

Score 1: slight change in color and texture.

Score 2: Marked change in color or texture and bleeding following superficial probing.

6) Probing depth:

Probing pocket depth was measured at the buccal, mesial, distal, and lingual aspects of the single tooth implant by plastic probe(Hu-friedy).

RADIOGRAPHIC ASSESSMENT

Radio visio graphs (RVG) of the implants were obtained after 2^{nd} stage surgery during cementation of the crown. The CCD (charge coupled device) of RVG was kept in precise orientation with bisecting angle technique and data was recorded. The assessment was carried out at 6^{th} month and 12^{th} month follow up visits. Radiographs were digitalized and analysed for peri-implant bone loss using sopro imaging software.

Measurements: (watzak. G et al., 2006)[68,39,69]

Peri-implant marginal bone loss mesial and distal to each implant was assessed by measuring the vertical distance between implant-abutment interface and the implant apex, also the bone level from the crest to implant

apex, also the bone level from the crest to implant apex. The difference between these two distances was defined as peri-implant bone loss.

To minimize the dimensional distortion, the apparent dimension of the implants were measured on the radiographs and divided by the actual implant size. corresponding bone loss in mm detected radiographically was divided by by the magnification factor to obtain the actual bone loss.

APPENDIX -1

Instructions to the Patient

1. Advised to follow the prescribed medication.
2. To perform regular oral hygiene habits by appropriate brushing technique using tooth brush and tooth paste.
3. 0.2% chlorhexidine gluconate rinse twice daily for 2 weeks after surgery.
4. In case of discomfort, patients were advised to report immediately.
5. Patients were instructed to maintain a soft diet for 4 weeks
6. The patients were dispersed and instructed to report at regular intervals.

APPENDIX -2

ARMAMENTARIUM

MATERIALS AND INSTRUMENTS USED FOR IMPLANT SURGERY:

- Gloves
- Mouth mask
- Patient apron
- Chair apron
- Head cap
- Sterile gauze
- Saline
- Betadine
- Kidney tray
- Lignocaine
- Syringe
- Mouth mirror
- Straight Probe
- Explorer
- William’s graduated periodontal probe
- Hu-Friedy plastic probe
- UNC 15 probe
- Ridge caliber
- Bone gauge
- Metal scale

- Bard Parker handle
- Bard Parker blade no 11, 15
- Periosteal elevator
- Tweezer, Tissue holding forceps
- Ultrasonic scalers
- Gracey Curettes
- Physio dispenser
- Implant kitS
- Surgical stent
- Soft tissue punch
- Dappen dish
- Healing abutment
- Plastic instruments
- Endo reamer
- Needle holder
- 3-0 suture material
- Cutting scissors

APPENDIX -3

PROFORMA

Op No : Date:

Name: Age:

Sex: Ph no:

Occupation:

Address:

Chief complaint:

Conventional flap Implant: ☐ flapless implant: ☐

Pre-surgical Medical History:

Pre-surgical Dental History:

Oral Hygiene Habits :

Materials used to clean the teeth:

If Brush:

1) Type of Brush

2) Paste/Powder/Others

3) Frequency of Brushing

4) Method of brushing

Pre-surgical Oral examination:

Extra Oral Examination:

Intra Oral examination:

Information on bone quantity: (Misch)

Type I

Type II

Type III

Type IV

Type of placement:

Implant Region:

Implant tooth site:

Adjacent Tooth:

Duration:

(Partial edentulous period for delayed implant/ Fractured or Grossly destructed tooth period for immediate implant)

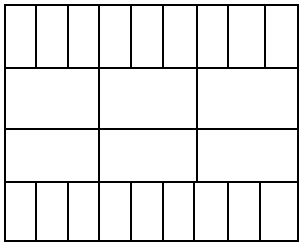
Implant size: Diameter: Length:

CLINICAL PARAMETERS

Oral Hygiene Status: (Plaque index, percentage)

Baseline:

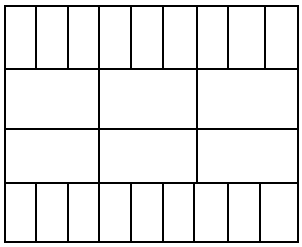
16 12 24



44 32 36 **SCORE** ☐

6th month:

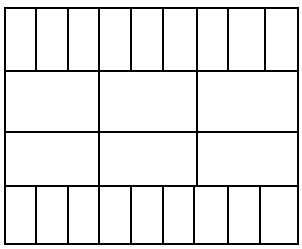
16 12 24



44 32 36 **SCORE** ☐

12th month:

16 12 24



44 32 36 **SCORE** ☐

Soft tissue conditions; (Mucositis score)

	Score level
Base line	
6th month	
12th month	

Width of keratinized gingivae: (Facial side**)**

	At mid line of the crown (in mm)
BaseLine	
6thmonth	
12th month	

Papilla index score; (Jemt. T, 1997)

	Mesial	Distal
Base line		
6th month		
12th month		

Thickness of peri-implant mucosa: (mm)

(2 mm below the gingival margin at the mid line of the crown)

	At the mid facial crown
Base line	
6th month	
12th month	

Probing depth: (mm)

	Mesial	**Distal**	**Buccal**	**Lingual**
Baseline				
6th month				
12th month				

Radiological assessment:

Peri-implant Bone Loss: (mm)

	Mesial	**Distal**
Base line		
6th month		
12th month		

CONSENT FORM

DEPARTMENT OF PERIODONTICS, JKK NATARAJA DENTAL COLLEGE, KOMARAPALAYAM- 638183

PATIENT NAME:

I have been explained about the nature and purpose of the study in which, I have been asked to participate. I understand that I am free to withdraw my consent and discontinue at any time without prejudice to me or effect on my treatment.

I have been given the opportunity to question about the material and study. I have also given the consent for photographs to be taken at the beginning, during and at the end of the study. I have fully agreed to participate in this study.

I hereby give the consent to be included in "**clinical and radiological evaluation of flapless delayed loading versus conventional delayed loading of implants in partially edentulous patients – one year randomized, prospective follow up study**, randomized, follow-up study.

Station:

Date :

SIGNATURE OF THE PATIENT

SIGNATURE OF PROFESSOR

STATISTICAL ANALYSIS METHOD:

In this study **Student *t* – distribution (William Sealy Gosset)** is used to analyze the significance between the groups at different time intervals.

The *t* –distribution is used when the sample size is small (less than 30) and standard deviation of the population is unknown.

Independent-Samples t Test

The Independent-Samples t Test procedure compares means for two groups of cases. Ideally, for this test, the subjects should be randomly assigned to two groups, so that any difference in response is due to the treatment (or lack of treatment) and not due to other factors.

According to this test,

The *t* – statistic is defined as

$$t = \frac{\overline{X} - \mu}{S} \times \sqrt{n}$$

Where

$$S = \sqrt{\frac{\sum (X - \overline{X})^2}{n-1}}$$

Whereas ***s*** is simple standard deviation of the sample and ***n*** is the sample size, the degree of freedom used is $n - 1$.

In the present study, $p > 0.05$ was considered as significant at 5% level of significance.

A total of 9 patients with 10 single tooth implants were participated in this study. In which five implants were placed in conventional flap reflection method and five implants were placed in flapless method. The implants were clinically and radiographically evaluated based on the implant placement.

Plaque index:

In flap group, the mean plaque index score at baseline was 0.94±0.21 that increased to 1.00 ±0.16 at the end of 6 months and 1.12±0.30 at 12 months. In flapless group at baseline, it was 0.66 ± 0.34 that increased to 0.78 ±0.34 at the end 6^{th} month and 0.84 ±0.33 at 12 months. On comparison between flap & flaplesss group, it was not statistically significant ($p>0.05$) as shown in table 1.

Soft tissue index:

In flap group, the mean soft tissue index at baseline was 0.142±0.31 that increased to 0.176 ± 0.38 at the end of 6 month and 0.224±0.034 at 12 months. In flapless group at baseline, it was 0.206±0.033 that increased to 0.284±0.006 at end of 6 months and 0.304±0.08 at 12 month. On comparison between flap & flapless group, it was statistically significant ($p <0.05$) as shown in table 2.

Width of peri-implant keratinized mucosa:

In flap group, the mean width of keratinized mucosa at baseline was found to be 5.66±0.47 mm that increased to 5.78±0.38 mm at the end of 6^{th} month and 5.88±0.38 mm at 12^{th} month. In flapless group at baseline, it was

5.70±0.29mm that increased to 5.92±0.33 mm at the end of 6th month and 5.98±0.22 mm at 12th month. On comparison between flap & flapless group, it was not statistically significant (p>0.05) as shown in table 3.

In percentage, the flap group showed 5.8% increase and in flapless group it was 4.91 % at 12th month as shown in table 8.

Thickness of peri-implant mucosa:

In flap group, the mean thickness of mucosa at baseline was found to be 2.12±0.179 mm that increased to 2.32±0.192 mm at the end of 6th month and 2.58 ±0.239 mm at 12th month. In flapless group at baseline, it was 2.34±0.207 mm that increased to 2.54 ± 0.207 mm at the end of 6th month and 2.72± 0.148 mm at 12 months. On comparison between flap & flapless group, it was not statistically significant (p>0.05) as shown in table 4.

In percentage the flap group, it was increased to 21.7% and in flapless group it was increased to 17.04 % at 12th month as shown in table 8.

Papilla index:

In flap group, the mean papilla index at baseline was found to be 3.8±0.447 that increased to 4.04 ±0.365 at the end of 6 month and 4.2±0.339 mm at 12th month. In flapless group at baseline, it was 4.3±0.274 that increased to 4.7±0.187 at the end of 6th month and 4.84 ±0.089 at 12th month. On comparison between flap & flapless group, it was statistically significant (p<0.05) as shown in table 5.

In percentage the flap group, it was improved to 10.53 % and in flapless group it was improved to 12.56 % at 12th month as shown in table 8.

Probing depth (PD):

Flap group:

The mean PD **mesially,** at baseline was found to be 1.26±0.182 mm that decreased to 1.2±0.158 mm at the end of 6th month; 1.16 ±0.134 mm at 12 month. **Distally** at baseline, it was 1.42 ±0.084 mm that decreased to 1.32 ±0.084 mm at the end of 6 month; 1.2±0.1 mm at 12 month**. Buccally** at baseline, it was 1.34±0.114 mm that decreased to 1.28±0.11mm at the end of 6 month; 1.26±0.114 mm at 12 month. **Lingually** at baseline, it was 1.34 ±0.114 mm that decreased to 1.28 ±0.084 mm at the end of 6 month; 1.08 ±0.11 mm at 12 month as shown in table 7.

In percentage, **mesially, distally, buccally,** and **lingually** it was 5.56%, 15.49%, 5.79%, 0.02% reduction respectively as shown in table 9.

Flapless group:

The mean PD **mesially,** at baseline was found to be 1.08±0.084 mm that decreased to 1.02±0.045 mm at the end of 6th month and 1.02± 0.045 mm at 12 month. **Distally** at baseline, it was 1.28±0.084 mm that decreased to 1.18 ±0.084 mm at the end of 6 month; 1.06±0.089 mm at 12 month**. Buccally** at baseline, it was 1.16±0.152 mm that decreased to 1.08±0.13 mm at the end of 6 month; 1.08±0.084 mm at 12 month. **Lingually** at baseline, it was

1.16±0.114 mm that decreased to 1.26±0.089 mm at the end of 6 month; 1.08±0.084 mm at 12 month as shown in table 7.

In percentage, **mesially, distally, buccally,** and **lingually** it was 7.94%, 17.19%, 6.90%, 11.9%, reduction respectively as shown in table 9.

Peri-implant bone loss:

In flap group, the mean peri-implant bone loss at baseline was found to be 1.02±0.164 mm that decreased to 0.8±0.1 mm at the end of 6^{th} month and 0.66±0.114 mm at 12^{th} month. In flapless group at baseline, it was 0.8±0.158 mm that decreased to 0.62 ± 0.084 mm at the end of 6^{th} month and 0.48±0.084 mm at 12^{th} month. On comparison between flap & flapless group, it was statistically significant ($p<0.05$) as shown in table 6.

In percentage the flap group there was 35.29% reduction and in flapless group it was 40.0 % at 12^{th} month as shown in table 8.

Table 1 Plaque index

Parameters	Flap	Flapless	P Value	Remarks
	Mean ± SD	Mean ± SD		
Baseline	0.94 ± 0.21	0.66 ± 0.34	0.078	Not Significant
6th month	1.00 ± 0.16	0.78 ± 0.34	0.12	Not Significant
12th month	1.12 ± 0.30	0.84 ± 0.33	0.054	Not Significant

Graph 1: Comparison of mean plaque index between flap & flapless groups at baseline, 6th and 12s th months

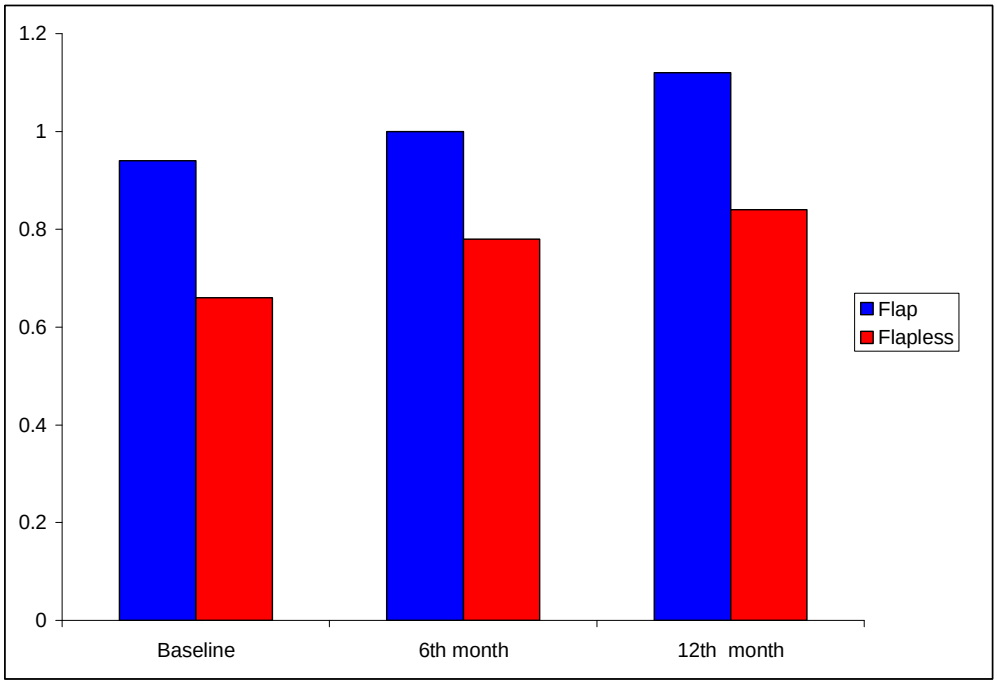


Table 2 Soft tissue index

Parameters	Flap	Flapless	P Value	Remarks
	Mean ± SD	Mean ± SD		
Baseline	0.142 ± 0.031	0.206 ± 0.033	0.007	Significant
6th month	0.176 ± 0.038	0.284 ± 0.006	0.015	Significant
12th month	0.224 ± 0.034	0.304 ± 0.08	0.047	Significant

Graph 2: Comparison of mean soft tissue index between flap & flapless groups at baseline, 6th and 12th months

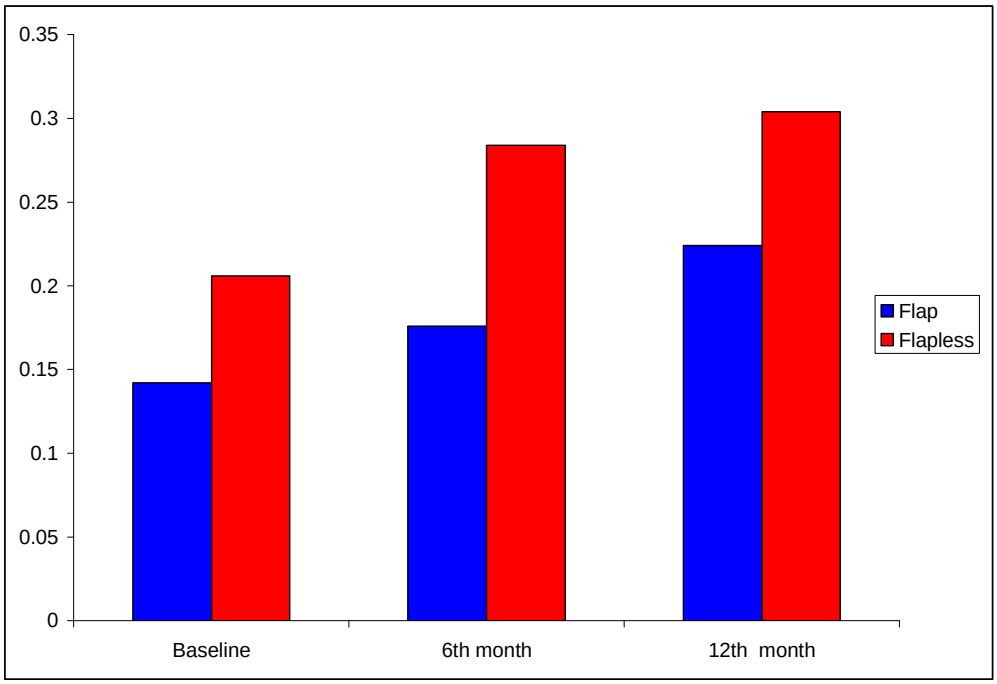


Table 3 width of keratinized gingiva

Parameters	Flap	Flapless	P Value	Remarks
	Mean ± SD	Mean ± SD		
Baseline	5.66 ± 0.47	5.70 ± 0.29	0.438	Not Significant
6th month	5.78 ± 0.38	5.92 ± 0.33	0.276	Not Significant
12th month	5.88 ± 0.38	5.98 ± 0.22	0.514	Not Significant

Graph 3: Comparison of mean width of keratinized gingiva between flap & flapless groups at baseline, 6th and 12th months

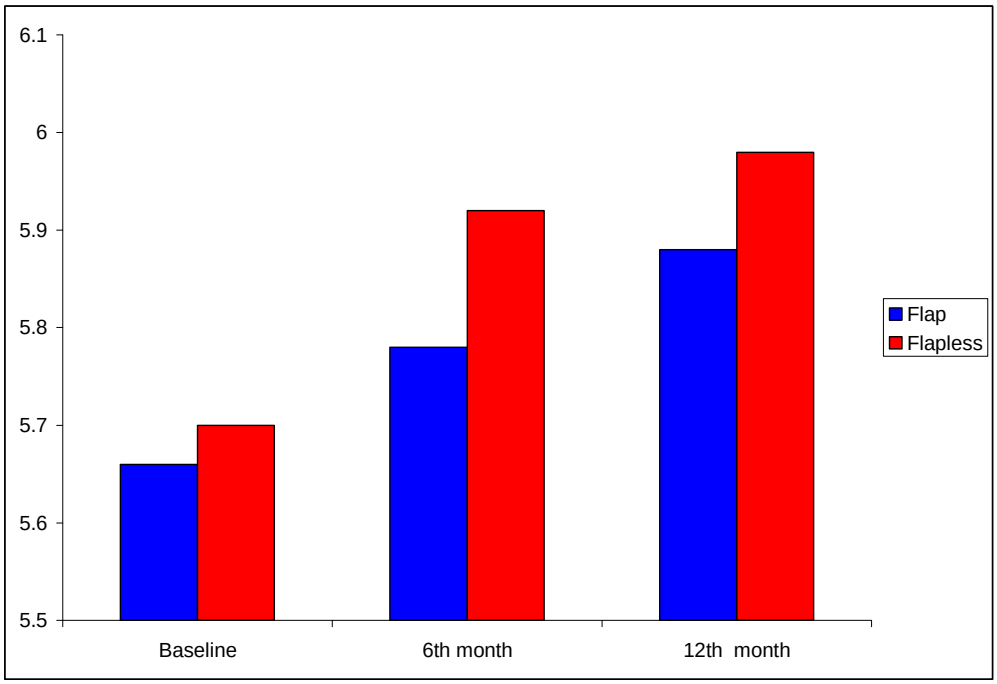


Table 4 Thickness of peri implant mucosa

Parameters	Flap	Flapless	P Value	Remarks
	Mean ± SD	Mean ± SD		
Baseline	2.12 ± 0.179	2.34 ± 0.207	0.055	Not Significant
6th month	2.32 ± 0.192	2.54 ± 0207	0.060	Not Significant
12th month	2.58 ± 0.239	2.72 ± 0.148	0.151	Not Significant

Graph 4: Comparison of mean thickness of peri implant mucosa between flap & flapless groups at baseline, 6th and 12th months

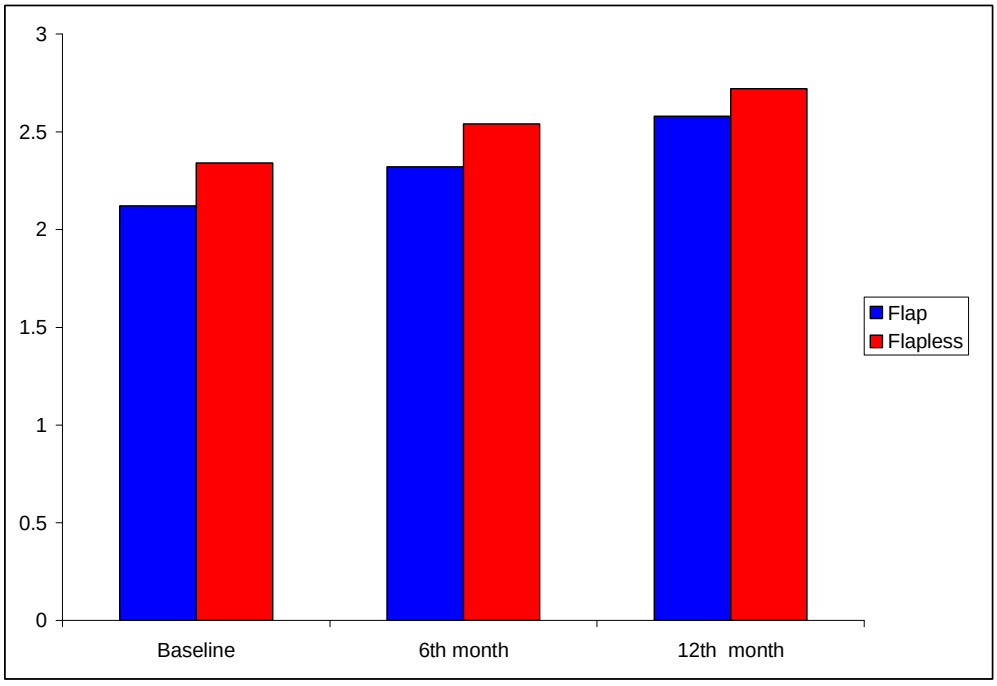


Table 5 Papilla index

Parameters	Flap	Flapless	P Value	Remarks
	Mean ± SD	Mean ± SD		
Baseline	3.8 ± 0.447	4.3 ± 0.274	0.035	Significant
6th month	4.04 ± 0.365	4.7 ± 0.187	0.006	Significant
12th month	4.2 ± 0.339	4.84 ± 0.089	0.005	Significant

Graph 5: Comparison of mean papilla index between flap & flapless groups at baseline, 6th and 12th months

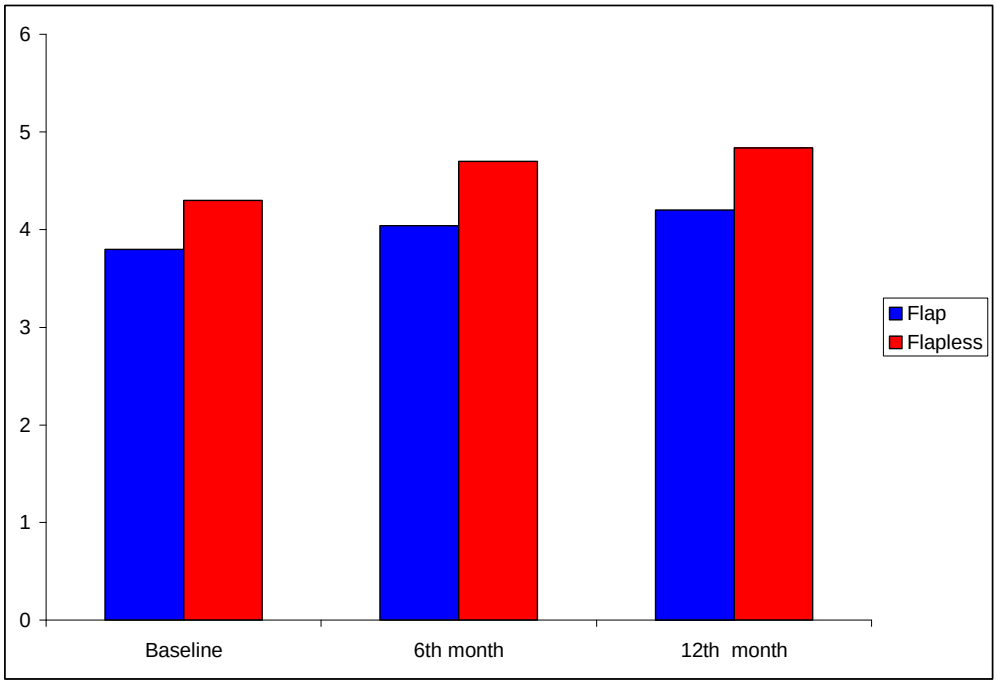


Table 6 Peri implant bone loss

Parameters	Flap	Flapless	P Value	Remarks
	Mean ± SD	Mean ± SD		
Baseline	1.02 ± 0.164	0.8 ± 0.158	0.032	Significant
6th month	0.8 ± 0.1	0.62 ± 0.084	0.007	Significant
12th month	0.66 ± 0.114	0.48 ± 0.084	0.012	Significant

Graph 6: Comparison of mean peri implant bone loss between flap & flapless groups at baseline, 6th and 12 months

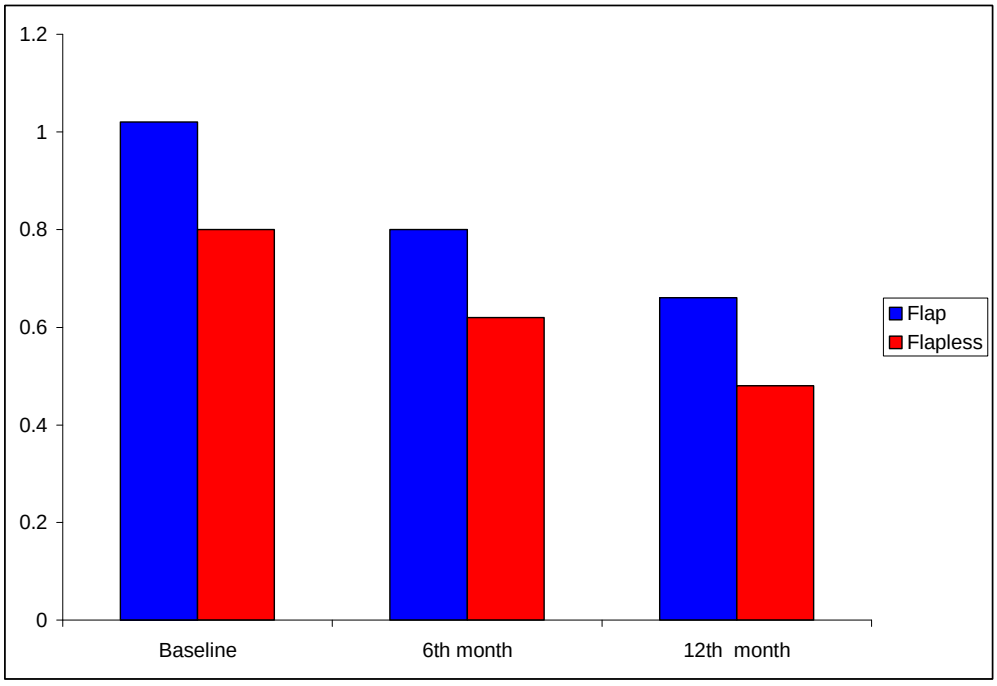
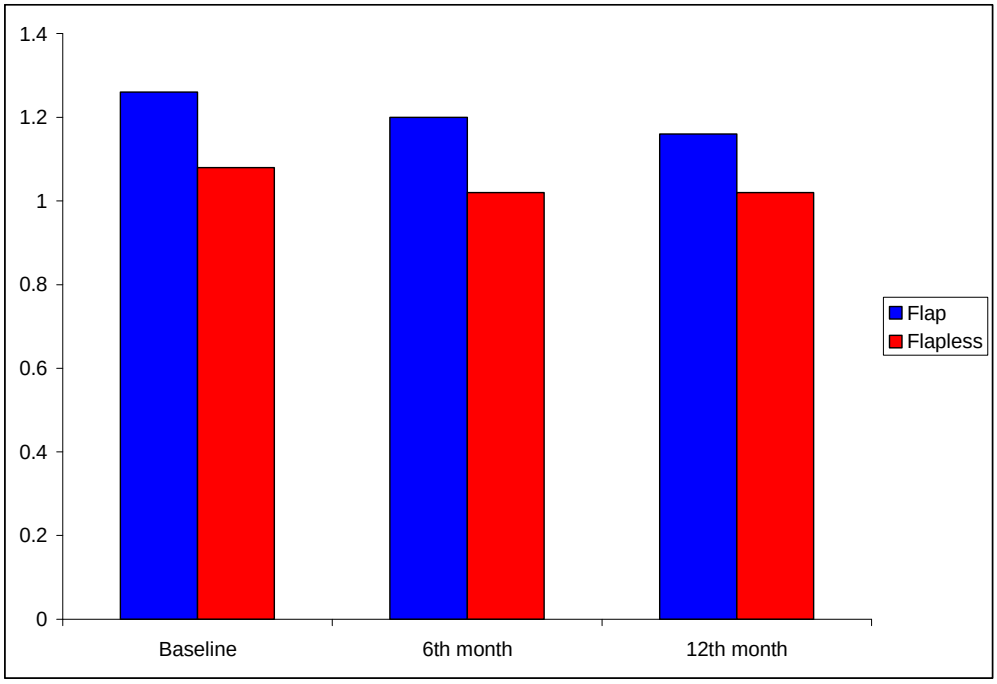


Table 7 Probing depth

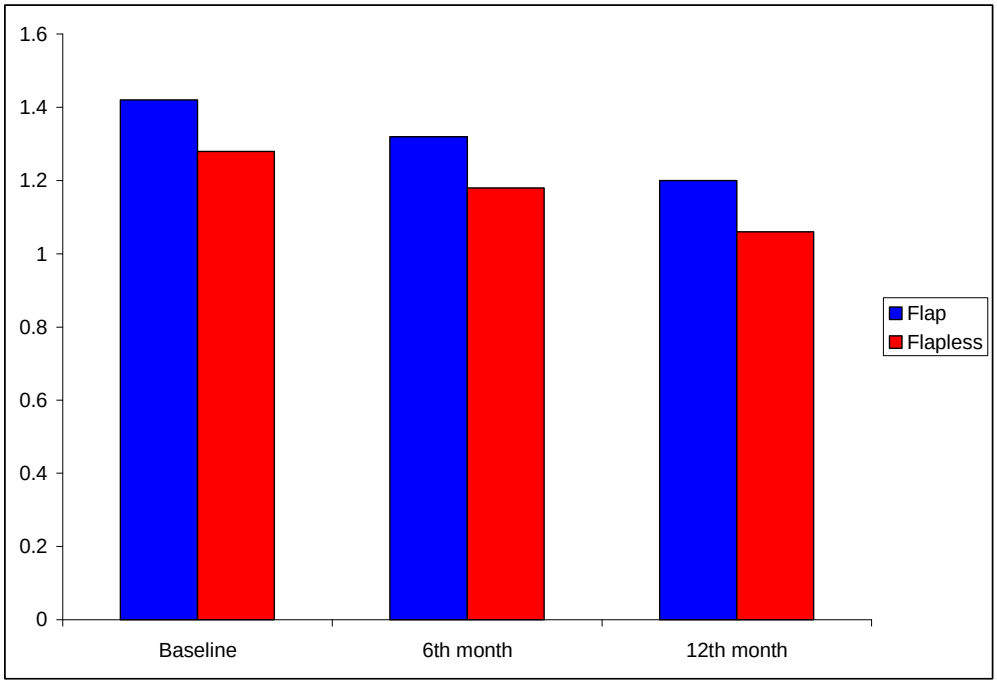
Parameters	Flap	Flapless	P value	Remarks
	Mean ± SD	Mean ± SD		
Mesially				
Baseline	1.26 ± 0.182	1.08 ± 0.084	0.045	Significant
6th month	1.2 ± 0.158	1.02 ± 0.045	0.029	Significant
12th month	1.16 ± 0.134	1.02 ± 0.045	0.039	Significant
Distally				
Baseline	1.42 ± 0.084	1.28 ± 0.084	0.015	Significant
6th month	1.32 ± 0.084	1.18 ± 0.084	0.014	Significant
12th month	1.2 ± 0.1	1.06 ± 0.089	0.024	Significant
Buccally				
Baseline	1.34 ± 0.114	1.16 ± 0.152	0.036	Significant
6th month	1.28 ± 0.11	1.08 ± 0.13	0.015	Significant
12th month	1.26 ± 0.114	1.08 ± 0.084	0.048	Significant
Lingually				
Baseline	1.34 ± 0.114	1.16 ± 0.114	0.019	Significant
6th month	1.28 ± 0.084	1.26 ± 0.089	0.008	Significant
12th month	1.08 ± 0.11	1.08 ± 0.084	0.047	Significant

Graph 7: Comparison of mean probing depth between flap & flapless groups at baseline, 6th and 12 months

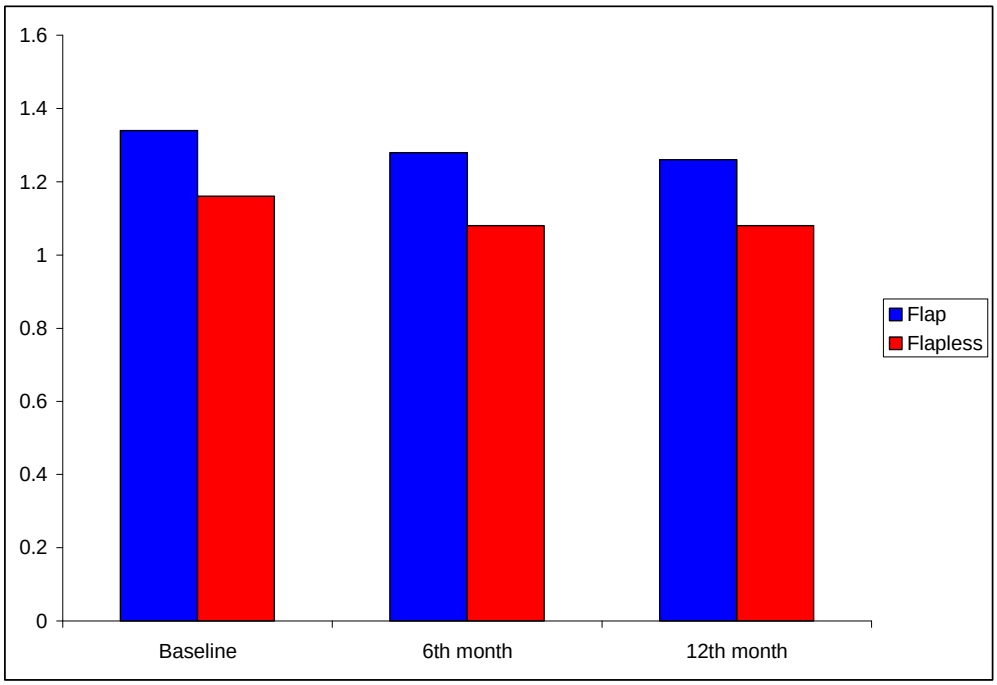
Mesially



Distally



Buccally



Lingually

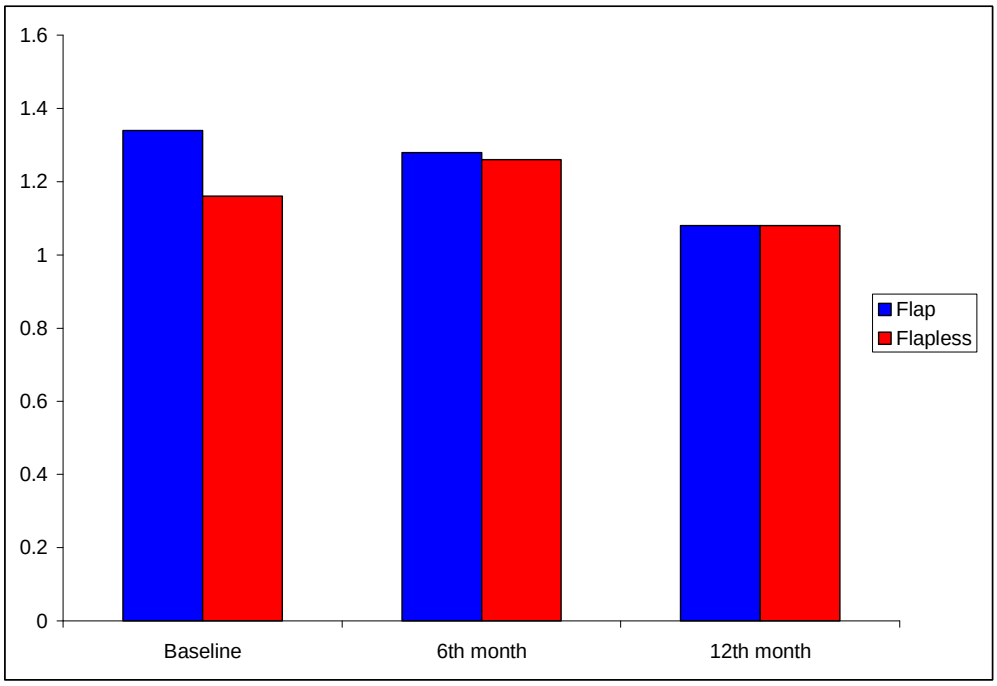


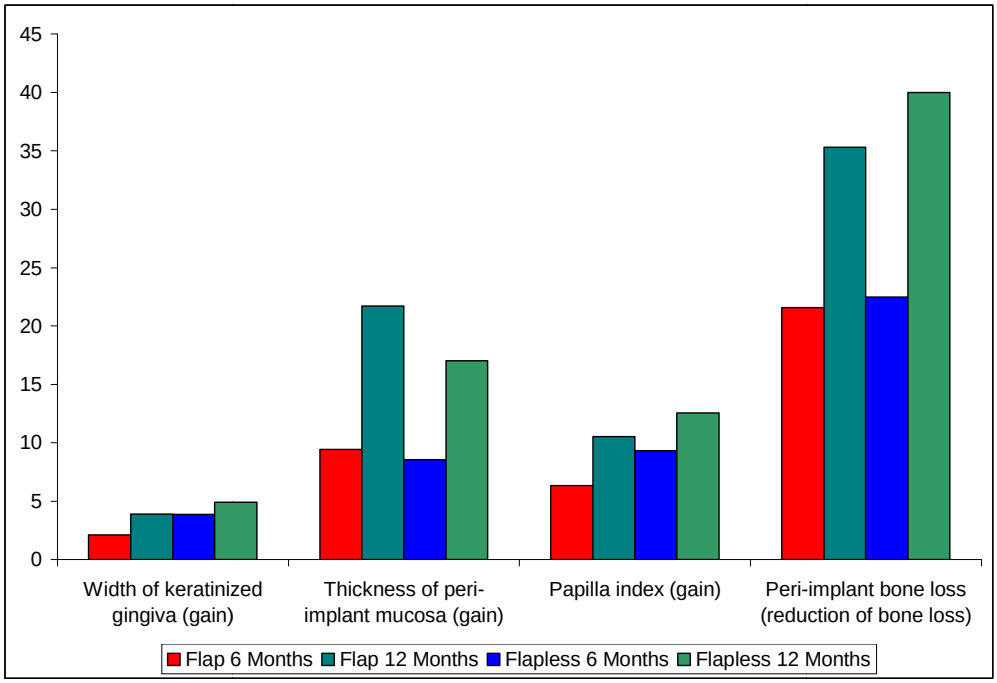
Table 8: flap and flapless group difference in (%) percentage of width, thickness of mucosa, papilla index and peri-implant bone loss at baseline, 6 and 12 months

Parameters	Flap (%)		Flapless (%)	
	6 months	12 months	6 months	12 months
Width of keratinized gingiva (gain)	2.12	3.89	3.86	4.91
Thickness of peri-implant mucosa (gain)	9.43	21.7	8.55	17.04
Papilla index (gain)	6.32	10.53	9.30	12.56
Peri-implant bone loss (reduction of bone loss)	21.57	35.29	22.5	40.0

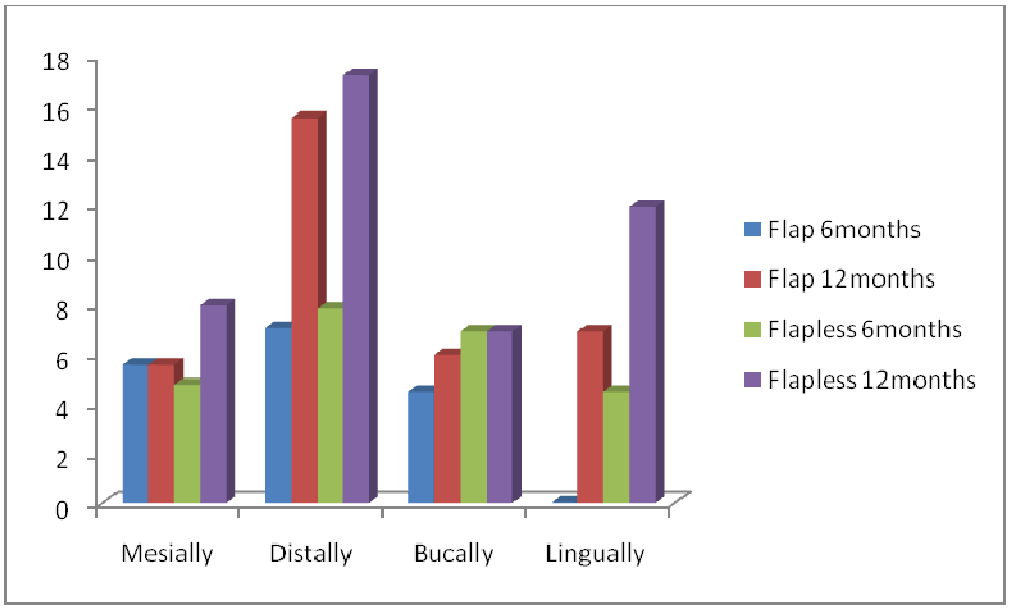
Table 9: flap and flapless group difference in (%) percentage of probing depth at baseline, 6 and 12 months

Pocket depth (reduction)	Flap (%)		Flapless (%)	
	6 months	12 months	6 months	12 months
Mesially	5.56	5.56	4.76	7.94
Distally	7.04	15.49	7.81	17.19
Bucally	4.48	5.97	6.90	6.90
Lingually	0.02	6.90	4.48	11.9

Comparison between groups in percentage level of width, thickness of mucosa, papilla ijndex and peri-implant bone loss



POCKET REDUCTION



The goal of modern dentistry is to return the patients to oral health in a predictable fashion. The single tooth implant survival rates have progressively improved.[69] The outcome of these implants depends on aesthetics, soft and hard tissue changes, patient satisfaction and complications.With advancement in implant dentistry, more progressive treatment strategies have developed either in placement or loading of the implants.

Clinician and patient dependent factors may play an important role in the aesthetic outcome of the single tooth implants.[70] Clinician dependent factors were included proper three dimensional implant positions and angulation, as well as appropriate contour of the provisional restoration. Patient dependent factors were included bone level, hard and soft tissue relationship, bone thickness, and soft tissue biotype.

Present study was conducted to evaluate the two methods of implant placement. The first method was conventional delayed loading of implants and the second method was flapless delayed loading of implants.

In this study, there was no statistically significant ($p>0.05$) mean plaque score difference, found between groups at baseline, 6 and 12 months. This proves that the patients oral hygiene gradually decreased at follow-up time during 6 and 12 month period. This is in accordance with Weber HP et al. (2000) and Renvert S et al. (2009)[71] study showed the same results and explained the lack of oral hygiene maintenance. Despite the fact that proper plaque control, elimination of peri-implant mucosal inflammation, control of gingival and periodontal disease of adjacent teeth are considered to be essential for the long term maintenance of implants.[72]

In this study, there was no statistically significant ($p>0.05$) difference in the width of keratinized mucosa were found in between groups at baseline, 6 and 12 months. But there was a significant percentage difference found between two groups, in which flapless group had more significant difference of 4.91 % gain. These results concur with the studies done by **Bouri et al.** (2008)[16], who observed that wider zone of keratinized mucosa (>2mm) had less plaque accumulation and mucosal inflammation. This wider zone had more resistant to forces of mastication and frictional contact that occurs during oral hygiene procedure. This is agreed with present results because no recession and inflammation was noted.

In this study, there was no statistically significant ($p>0.05$) difference in mean thickness of per-implant mucosa were found between groups at baseline, 6 and 12 months. Flap and Flapless groups had greater than 1mm of mucosa thickness which was classified under thick biotype. In this current study, no statistical difference was found in thickness of mucosa between groups. But on clinical examination, significant mucosal thickness was noticed after the crown placement. **Henrikkson et al.** (2004) found the same results and also proved significant increase in the buccal volume of peri-implant tissue after crown placement**. Kan JYK et al. (2004)**[73] described the gingival biotype as being thick or thin. A thick biotype implies more fibrotic tissue, more vascularization that was more resistance to recession. Thin gingival tissue has less underlying bone support and blood supply had more chance of recession. This agreed with our results that all gingival biotype in the study has greater than 1mm thickness with no recession. but there was a significant

percentage difference between two groups, in which flap group had more significant difference of 21.7 % gain comparing 17.04% gain in flapless group.these results are similar with the studies of **BYUNG et al (2009)**[51,52] that the mucosa around the implants are more abundant at flap sites causes due to the scarring after flap reflection than at flapless sites.[74]

In this study, there was statistically significant difference ($p<0.05$) in mean papilla index were found between groups at baseline, 6 and 12 month. There was a significant percentage difference found between the two groups . In this study, the improved papilla fill was observed from the time of crown placement to 1 year period ,more in flapless group than flap group that was 10.53% in flap implants and 12.56% in flapless implants. This finding is agreeing with previous reports found in the literature (Jemt 1997, 1999; Chang et al. 1999; Choquet et al. 2001). The study done by **CHOQUET et al. (2001)**[26,28,14] in the regeneration of gingival papilla shows that bone level is directly interrelated to papilla regeneration.

In this study, there was statistically significant ($p<0.05$) difference in mean probing depth were found between groups at baseline, 6 and 12 months. Probing depth was seen to be decreased from the time of crown placement to 12 months in both groups. Percentage of probing depth reduction was 5.56%,15.49%, 5.97%, and 6.90 % at mesially, distally, buccally and lingual sites for conventional flap group, compared with 7.94%, 17.19%, 6.90%, 11.9% at mesial, distal, buccal and lingual sites respectively in flapless group . In flapless group, a mean probing depth was less compared to flap group showed similar results with studies conducted by **Jeong et al. (2009**)[51,52] that

the pocket probing depth was significantly greater in the flap group than in the flapless group. .The mean probing depth in both group is 1.32. However, it is reasonable to assume that probing depth not exceeding 4.0 mm are preferable to facilitate the patient's ability for self-performed plaque control as well as accessibility for proper professional peri-implant cleaning.

Analysis of the crestal bone levels assessed on RVG (Radio Visio Graph) showed that bone loss occurred at the proximal surfaces of implants within the observation period of present study in both the groups. The average mean bone loss was 0.66 mm in the flap group and 0.48 mm in the flapless group from the crown placement to 12 months period. These results concur with the study done by **JEONG et al.(2009)**[49-52] who evaluated flap and flapless implants in his study showed that the radiographic evaluation demonstrated that there was a small amount of bone loss during the healing process in the flap group, where as there was no visible bone loss in the flapless group.. The present results also meet the success criteria for implant treatment proposed, in the consensus report of the 1st European Workshop on Periodontology: "The criteria of success include average bone loss of less than 1.5 mm during the first year after insertion of the prostheses" **(Albrektsson & Isidor 1994).**[49-52]

Thus the success rate and aesthetic outcome of single tooth implants placed either anterior or posterior region in the present study had a favourable clinical and radialogical outcome using the two different placement methods. There was no statistically significant ($p>0.05$) difference was noted in plaque index, width of keratinized gingiva and thickness of mucosa between two

groups. There was statistically significant ($p<0.05$) difference was noted in papilla index, pocket probing depth, bone loss and soft tissue index between the groups.

However, limitations of this study included,

- Small sample size
- Implant placed irrespective of anterior or posterior region
- No contralateral sites were selected
- Lack of implant stability test

In order to evaluate the proper clinical parameter and biological osseointegration, a study design of larger sample size with proper selection of the patient would be needed.

The study was designed and conducted in the Department of Periodontics, JKK Nattraja Dental College and Hospital, komarapalayam, Tamilnadu.

In this one year, study was done to evaluate the clinical and radiological parameters of 5 flap and 5 flapless single tooth implants in respect to the method of placement. All the patients were followed up for 6 and 12 months corresponding to a functional loading time of 4 months . All the implants were remained in function during one year after the crown restoration.

The Plaque index, soft tissue index, probing depth, width of keratinized mucosa, thickness of peri-implant mucosa, papilla index and peri-implant bone loss were recorded at baseline, 6^{th} and 12 months intervals. The peri-implant bone loss was assessed by using RVG by sopro imaging software. The data were subjected to statistical analysis. From the results obtained, the following conclusions were arrived:

1. Single tooth implant revealed higher success rates in both groups with positive tissue response.
2. The minimum 1mm thickness of peri-implant mucosa is needed for maintaining the implants without recession.
3. Peri-implant inflammation was less for implants surrounded by more than 2mm of keratinized mucosa in both groups.
4. Improved papilla fill was observed in flapless group than in flap group
5. Average peri-implant bone loss in both groups was less than 1.5 mm after the 12 year period of function .bone loss is much lesser in flapless group comparing to flap group.

6. Pocket probing depth also lesser in flapless group comparing to flap group.

The results obtained here clearly demonstrated that self-threaded internal hex, titanium implants placed according to a flap or flapless surgical protocol can be predictably successful over a period of 12 months. High successful rates were achieved without severe peri-implant complications.

However, it is necessary to have a large sample size with proper selection of the patients needed to evaluate the clinical and radiological parameters. Also further studies need to be carried out to evaluate the relationship between peri-implant soft and hard tissue in respect to the placement of implants.

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ARMAMENTARIUM

Physiodispensor & implant kit

Surgical instruments

PRE OPERATIVE EVALUATION

FLAP – CASE 1 (TOOTH NO. 36)

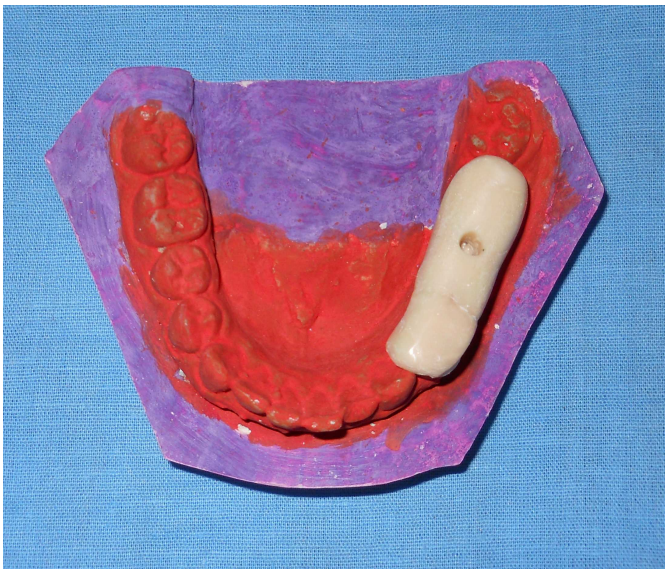
PRE OPERATIVE VIEW

OPG WITH RADIOGRPAHIC STENT

CAST WITH RADIOGRAPHIC STENT

BONE MAPPING - CAST

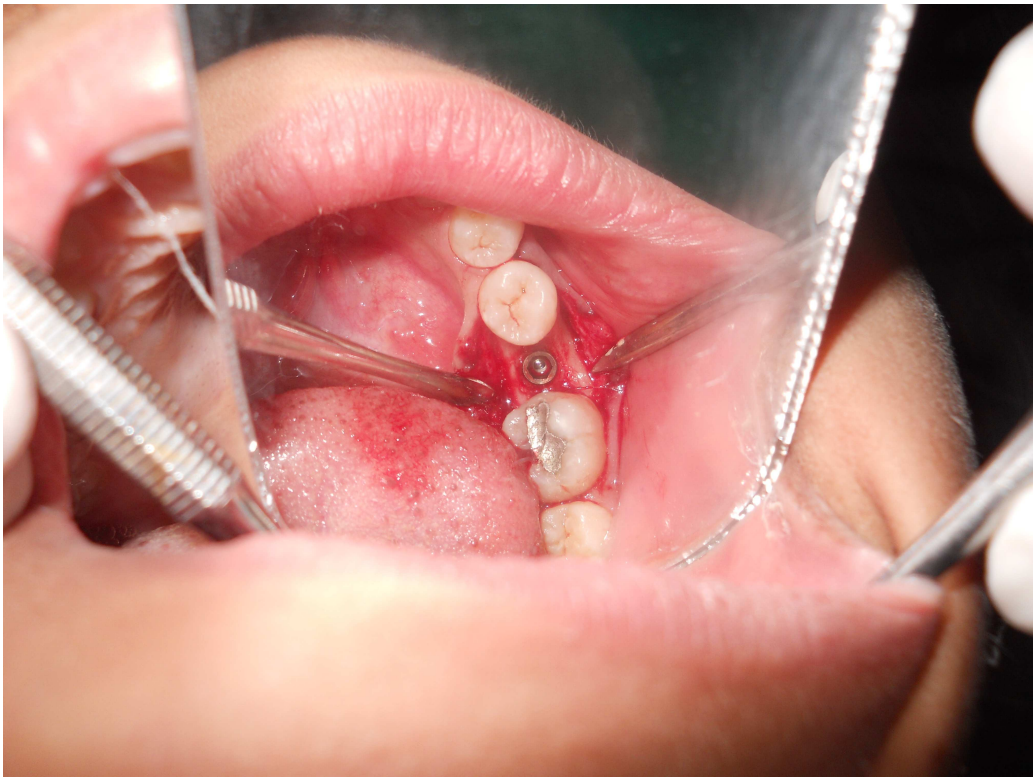
CAST WITH SURGICAL STENT



OPERATIVE VIEW

PARALLELING TOOL PLACED

IMPLANT PLACED



COVER SCREW PLACED

SUTURING PLACED

HEALING AFTER 3 MONTHS

OPERATIVE VIEW

HEALING ABUTMENT PLACED

HEALING ABUTMENT REMOVED (AFTER 3 WEEKS)

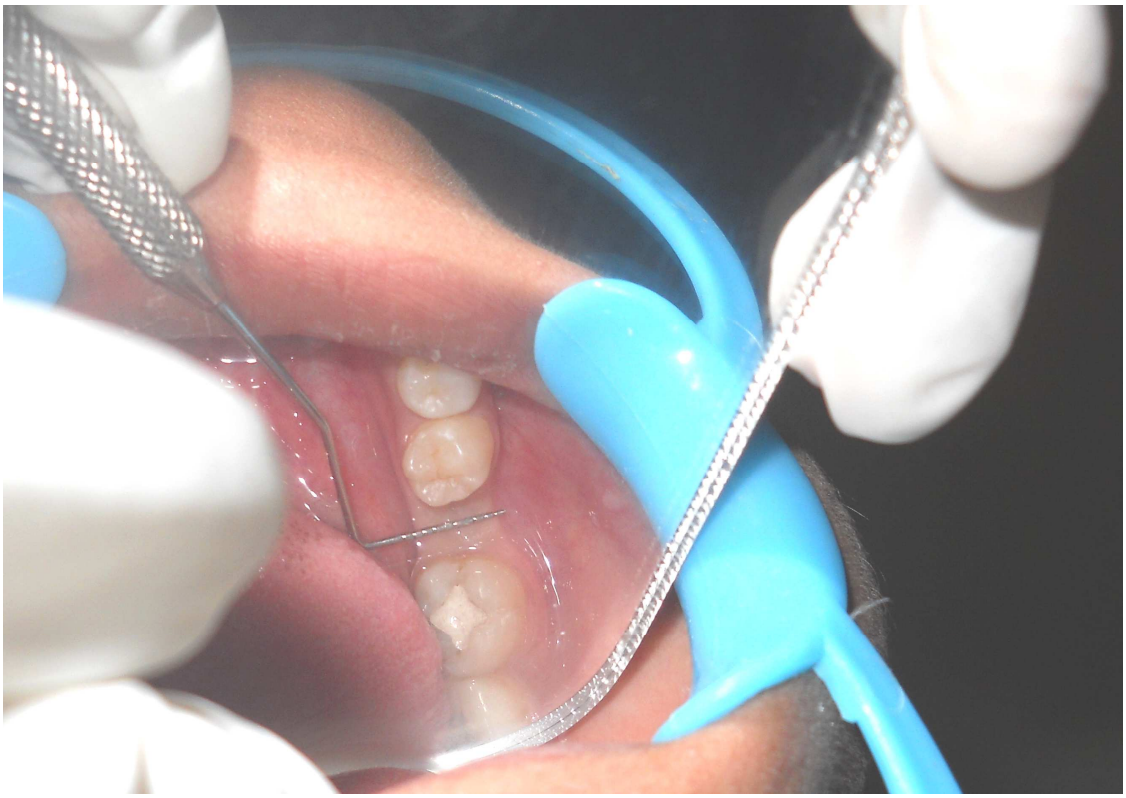
FINAL ABUTMENT PLACED

CEMENTATION OF PROTHESIS

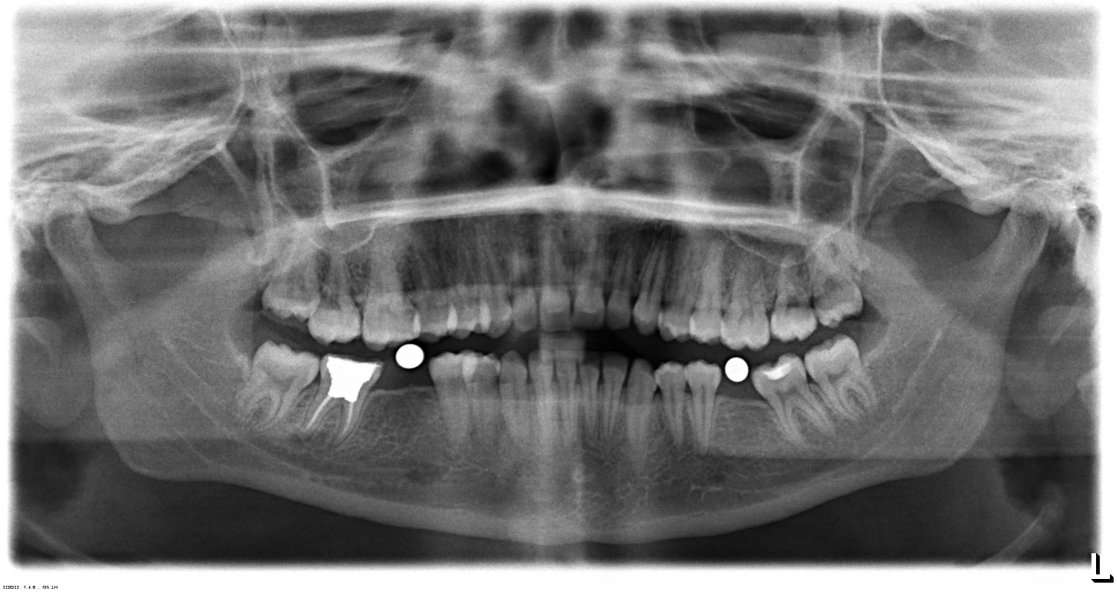
PRE-OPERATIVE EVALUATION

FLAPLESS - CASE – 2 (TOOTH NO. 36)

PRE-OPERATIVE VIEW



OPG WITH RADIOGRAPHIC STENT



CAST WITH RADIOGRAPHIC STENT

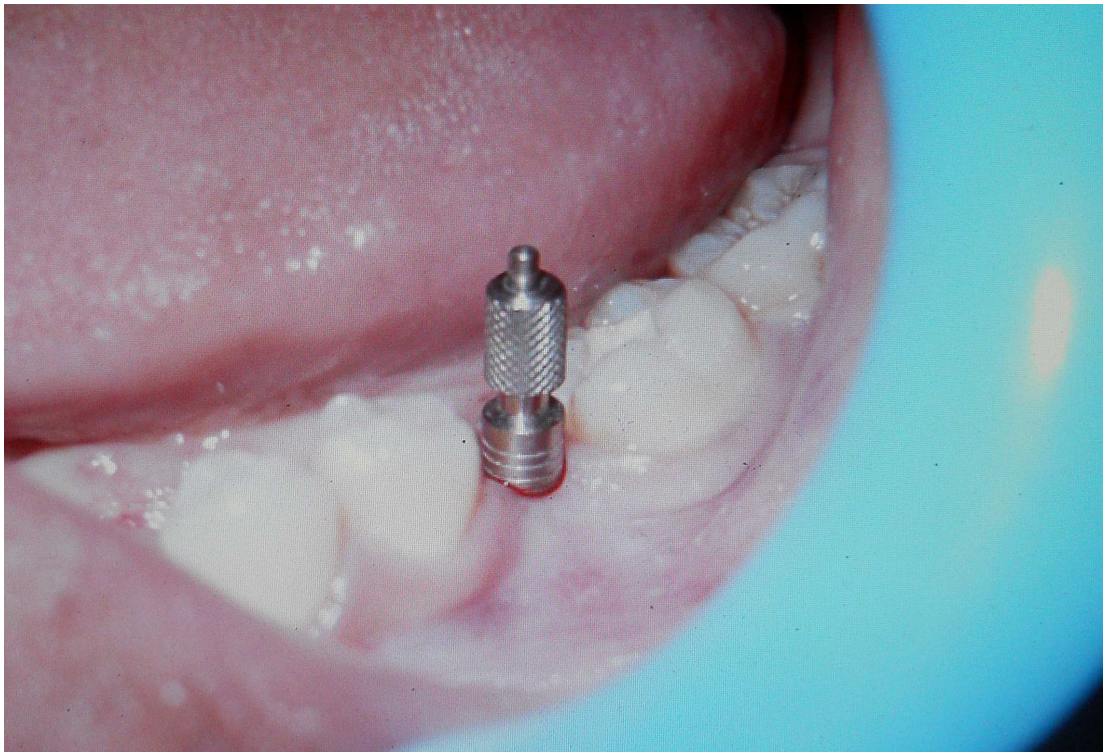
CAST WITH BONE MAPPING

CAST WITH SURGICAL STENT

BONE MAPPING

SURGICAL STENT

SOFT TISSUE PUNCH PLACED



OPERATIVE VIEW

PARALLELING TOOL PLACED

IMPLANT PLACED IN 36

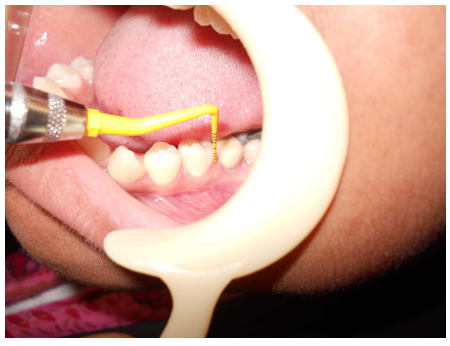
HEALING ABUTMENT PLACED

HEALING CAP REMOVED (AFTER 3 MONTHS)

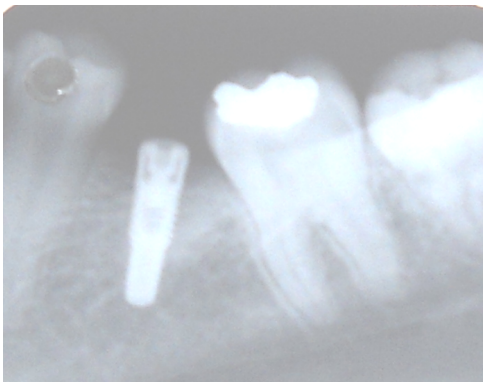
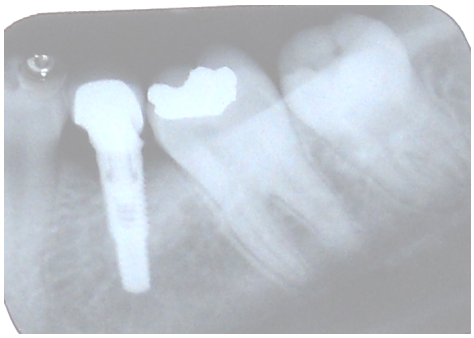
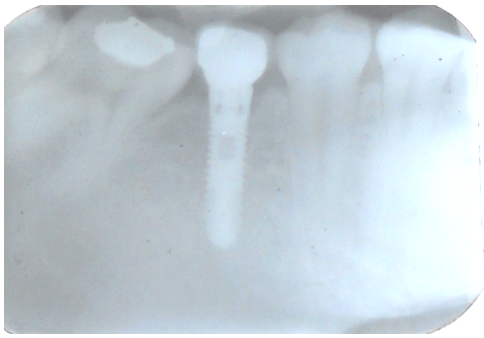
FINAL ABUTMENT PLACED

CEMENTATION OF PROSTHESIS

CLINICAL PARAMETERS

CASE 1	CASE 2
Flap - Base Line  **Width of Keratinized Mucosa(mm)**	**Flapless – Base Line**  **Width of Keratinized mucosa (mm)**
 **Thickness of Mucosa (mm)**	 **Thickness of Mucosa (mm)**
 **Papilla Index (Score)**	 **Papilla Index (Score)**
 **Probing Depth (mm)**	 **Probing Depth (mm)**

RADIOLOGICAL PARAMETERS

CASE 1	CASE 2
Flap – IOPA at placement	**Flapless – IOPA at placement**
	
IOPA at baseline	**IOPA at baseline**
	
RVG at Base line	**RVG at Base line**